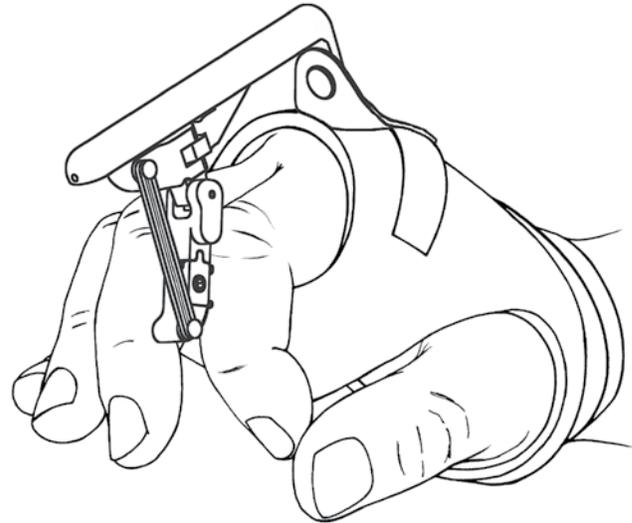


Agee Digit Widget[®]

External Fixation System

For treatment of PIP joint flexion contractures.
Maintenance of joint extension depends on identification and treatment of force imbalance causing contracture.



Surgeon's Manual



Digit Widget® External Fixation System

Item No. DWD-232

United States Patents 6,063,087; 6,565,563;
and 6,592,584

Surgeon's Manual, Part No. 320401B, 1/15
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How To Use This Manual

Cautions and Warnings

Errors

Although a careful effort 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 Digit Widget or its proper installation.

Organization

This Surgeon's Manual is organized in four main sections that correspond to the installation procedure. Please read the entire manual before using the Digit Widget.

- Introduction
- Surgical Installation
- Post-Surgical Assembly
- Clinical Course

Precautions

General device warnings and cautions appear within the Indications, Contraindications and Device Precautions 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 user 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 Devices Used in Home Health Care. HHS Publication FDA 93-4258 (August 1993) (64pp.).

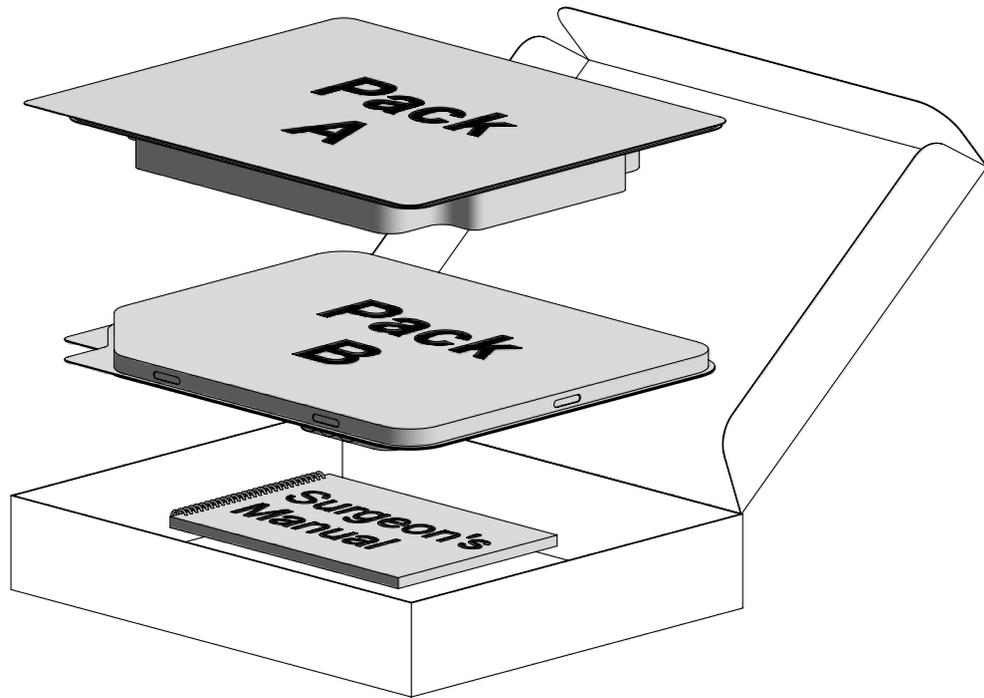


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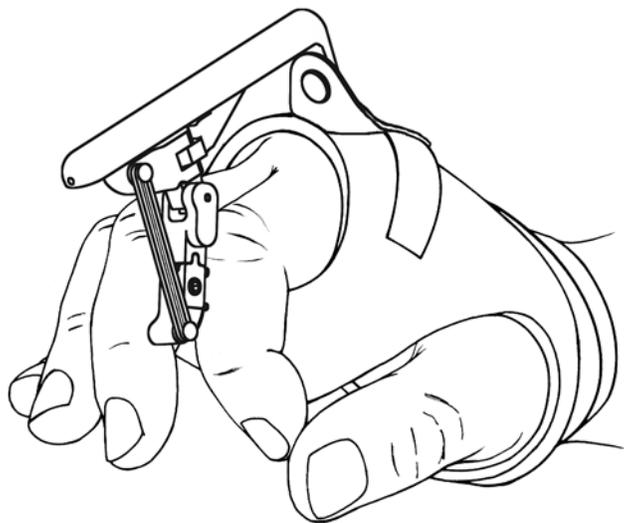


Figure 1: Installed Digit Widget

Introduction

A letter from John M. Agee, M.D.

Dear Colleague,

One of the most frustrating problems we face as hand surgeons is a flexion contracture of the proximal interphalangeal (PIP) joint.

The most effective means of reversing a flexion contracture is to generate an extension torque about the PIP joint. With conventional splints it is difficult to apply an effective torque without causing pain and inflammation due to pressure on the skin. The amount of force used to reverse the contracture is limited by the ability of the skin and soft tissues to tolerate pressure at the skin-splint interface.

Frequently, serial plaster casting of a PIP joint contracture is effective because it distributes pressure to the skin over a large area. Because of this, a cast can usually be worn 24 hours a day. This prolonged wearing time results in increased extension because it gives the contracted tissues time to “grow”, but it also prevents flexion of the involved finger and may result in decreased flexion of the adjacent fingers.

We began design of the Digit Widget knowing that the joint and its associated soft tissue contracture will accept a higher force if it is applied by a method that transmits the force directly to the skeleton. We designed the device to exert an extension torque across the PIP joint while avoiding the skin pressure and limited range of motion issues associated with dynamic splints and serial plaster casts. Because the Digit Widget creates a torque using forces transmitted through the skeleton, there is no pressure on the skin of the finger. The device permits full flexion of the finger and thereby encourages functional use of the hand during treatment. The magnitude of the extension torque can be easily adjusted to improve joint extension while avoiding joint inflammation from excessive torque.

The goal of treatment is to provide the least torque necessary for a progressive increase in joint extension. A modest extension torque stimulates “growth” of soft tissues palmar to the axis of rotation of the PIP joint. Excessive torque creates ischemia of stretched palmar tissues resulting in pain, stiffness and edema. This edema is detrimental to restoring joint motion.

Introduction

Shortening of palmar soft tissues is secondary to a force imbalance around the joint. This may be an increase in flexor forces or a loss of extensor forces, or a combination of the two. The Digit Widget is a tool to help restore length to the palmar tissues. Although it can improve extension, this improvement will not be maintained if the Digit Widget is not part of a treatment plan that restores balance to the flexor and extensor forces that cross the joint. Successful reversal of a PIP joint contracture requires a joint surface that is anatomically intact.

Each patient's treatment is best monitored by plotting change in range of motion as a function of time. When the graph shows diminishing gains in extension and the joint is not painful or inflamed, then band tension (torque) can be increased. Conversely, if a given torque is accompanied by increasing pain, swelling and inflammation, then combinations of rest and decreased torque are appropriate.

The graphed range of motion will help you identify:

- The rate of restoration of extension.
- A plateau of extension. This may indicate rigid, non-compliant soft tissues such as scar or a

mechanical block such as a non-gliding joint surface.

- A significant loss of flexion. This may indicate excessive force with secondary joint inflammation, edema and potential for aggravating joint stiffness.
- The appropriate time for device removal.

Graphs that depict change in range of motion over time combined with serial examinations of the joint will help you select the optimal torque the joint can accept to restore extension without compromising finger flexion. We have included forms if you or your hand therapist would like to graph the patient's progress.

We have worked hard to make the Digit Widget a patient and surgeon friendly tool to aid in your treatment of PIP flexion contractures. The patient's ultimate outcome will depend on the etiology of the deformity and the overall treatment plan for correcting it.

As always, we welcome your comments and questions.

John M. Agee, M.D.

Introduction

Digit Widget Description

Design

The Digit Widget is an external fixation system designed to apply an extension torque to the Proximal Interphalangeal (PIP) joint of a finger. This device helps regain, maintain, or increase extension of the PIP joint. The patient can actively exercise and use the finger while an extension torque is gently lengthening the contracted tissues on the palmar side of the joint. It utilizes small diameter Bone Pins to surgically secure the device to the dorsal side of the middle phalanx.

The surgeon or hand therapist (under order from the surgeon) can adjust the amount of extension torque by changing the strength or number of Elastic Bands. In general, the torque is initiated with the lowest tension Elastic Band and this tension is maintained at all times except to wash the hand or bathe. If joint extension, as monitored by time and goniometric measurement, does not progressively increase, then the tension of the Elastic Band may be increased.

Excessive extension torque is typically accompanied by pain, swelling, inflammation, and loss of total range of motion. Patient education and careful clinical monitoring

are important to define an extension torque optimal for increasing motion while minimizing inflammation that can compromise treatment. The Elastic Band can be removed intermittently to facilitate active range of motion exercises.

Materials

The Digit Widget external fixator is manufactured using plastic and metal. The Bone Pins are fabricated from 316L stainless steel. The Cuff is made of neoprene and nylon, with hook and loop attachments. **Warning: The Elastic Bands in this product contain natural rubber latex which may cause allergic reactions.** All components are designed for single use only.

Instrumentation and Sterilization

The Digit Widget System is provided in two packs. Pack A contains **STERILE** components for surgical installation of the Bone Pins and Pin Block. Pack B contains **NON-STERILE** items necessary for complete assembly of the Digit Widget. No items in Pack B can be sterilized. All components are for **SINGLE USE** only.

Pack A: Surgery Components

- Condensed Surgical Guide (not pictured)
- Drill Guide
- Distal Pin and Pre-Drill
- Proximal Pin and Pre-Drill
- Digit Widget Pin Block
- Hex Wrench (5/64")

Pack B: Post Surgery Assembly (DO NOT STERILIZE)

- Condensed Assembly Guide (not pictured)
- Digit Widget Connector Assembly
- Elastic Bands (not pictured)
- Cuff (not pictured, two sizes included)
- MP Flexion Strap (not pictured)
- Hex Wrench (5/64")

CAUTION: Pack A tray and contents are STERILE unless packaging has been opened or damaged.

CAUTION: Pack B tray and contents should NOT be sterilized. They are not designed to withstand sterilization.

CAUTION: Do not reuse Digit Widget device, Pre-Drills or Bone Pins. They are not designed to safely withstand multiple patient use.

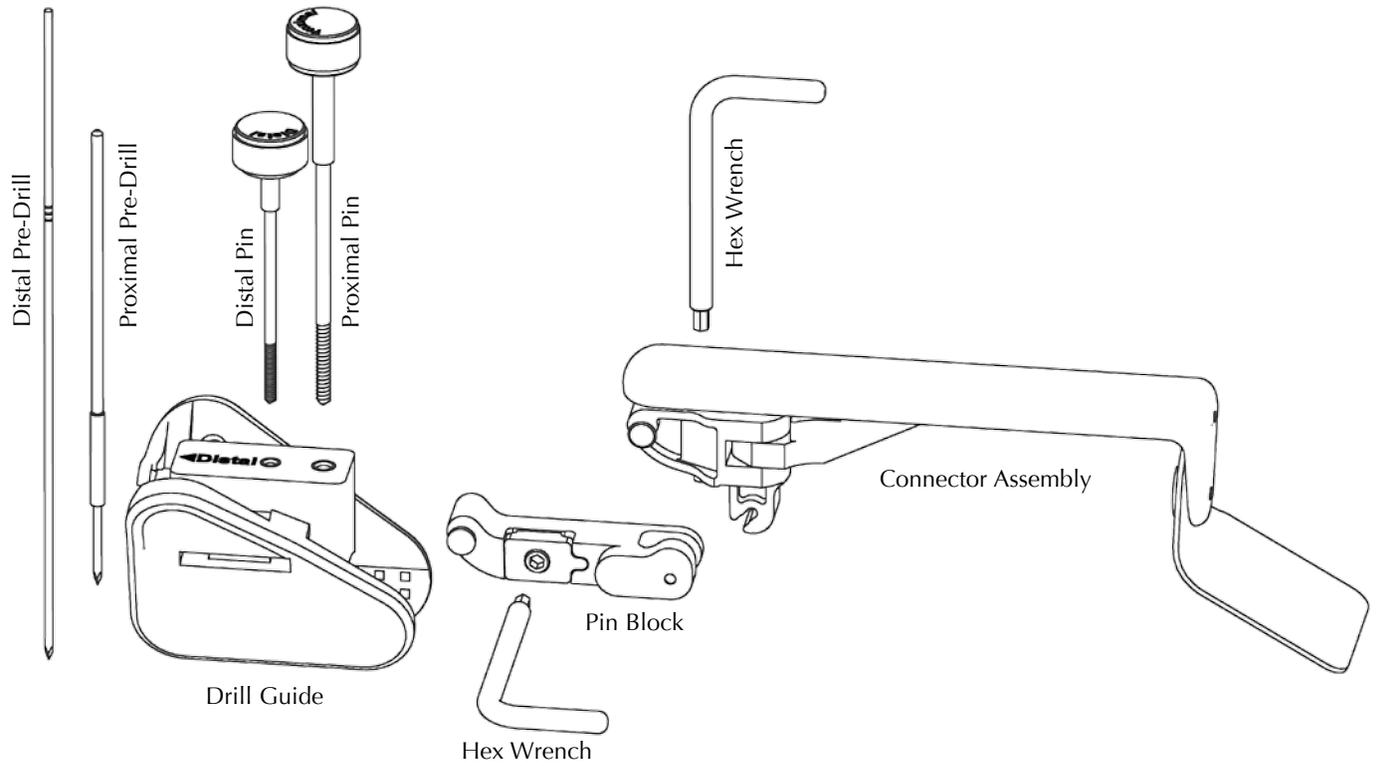


Figure 2: Fixator, Instrumentation, and Pins

Indications, Contraindications and Device Precautions

Indications For Use

The Digit Widget is indicated for treatment of proximal interphalangeal (PIP) joint flexion contractures. Maintenance of joint extension depends upon identification and treatment of force imbalance causing contracture.

Contraindications

The Digit Widget should not be used on uncooperative or mentally incompetent patients who are unable to follow the postoperative regimen.

Cautions (technique cautions noted with instructions)

1. Restoration of finger extension is not feasible for PIP joint contractures in which the joint surface is significantly impaired. Therefore, the Digit Widget should not be used for PIP joint contractures on patients with either osteoarthritis or post traumatic joints with residual joint incongruity. This includes subluxed joints such as those following healed dorsal fracture subluxations/dislocations. These abnormal joints typically demonstrate combinations of gliding and rocking motion that can be seen with lateral X-rays comparing joint congruity (alignment) following both maximum flexion and maximum extension.
2. If application of the Digit Widget is combined with a significant capsular (collateral) ligament release, the torque the device applies can produce a volar dislocation of the middle phalanx on the head of the proximal phalanx.
3. Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is important to proper device installation.
4. Patient cooperation and participation are important to effective Digit Widget use. Advise your patient to report adverse or unanticipated effects as soon as possible. Instruct the patient on proper selection and use of Elastic Bands, wearing requirements, device alignment and comfort adjustments.
5. Weekly postoperative follow-ups by the surgeon and/or hand therapist are recommended to monitor treatment.
6. 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.
7. If the patient develops a rash or skin irritation under the Cuff, a cotton stockinet may be worn under the Cuff.

Warnings (technique warnings noted with instructions)

1. Bone Pin placement requires strict anatomic considerations to avoid damage to nerves, blood vessels and tendons.
2. Pre-drilling should be done using a low speed drill to minimize heat that can injure bone or soft tissue.
3. Use caution when handling the sharp tips of the Bone Pins and Pre-Drills. The pin heads should be held when clipped. Eye protection is recommended for all operating room personnel.
4. As with all percutaneous skeletal fixation techniques, 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 and may cause allergic reactions.

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 which may extend to involve the entire finger.
4. Persistent joint contracture, loss of range of motion, joint subluxation or dislocation.
5. Loosening or breakage of the components.
6. Intractable pain.
7. Foreign body reaction to Bone Pins or other components.
8. Tissue necrosis occurring during Bone Pin insertion.
9. Excessive operative bleeding.
10. The intrinsic risks associated with anesthesia.
11. Sustained pressure across the joint surface has the potential to injure the joint's hyaline cartilage.



Surgical Installation

Complete installation of the Digit Widget is done in two steps. This section describes the surgical installation of the Pins and Pin Block. All components needed are enclosed in the sterile package labeled Pack A.

Final assembly of the device is done outside the sterile field. Instructions follow in the Post-Surgery section. Components needed for device assembly are enclosed in Pack B.

Surgical Installation

Overview

This X-ray depicts a correct surgical installation of the device. Using pre-drilled holes, the threaded pins are manually rotated through both cortices. Note the position of the pins. The Proximal Pin is just distal to the joint. The threaded tips of both pins extend through, but not beyond, the palmar cortex thereby avoiding flexor tendon injury. The device is clamped to the pins approximately 3/16" (5 mm) above the skin.

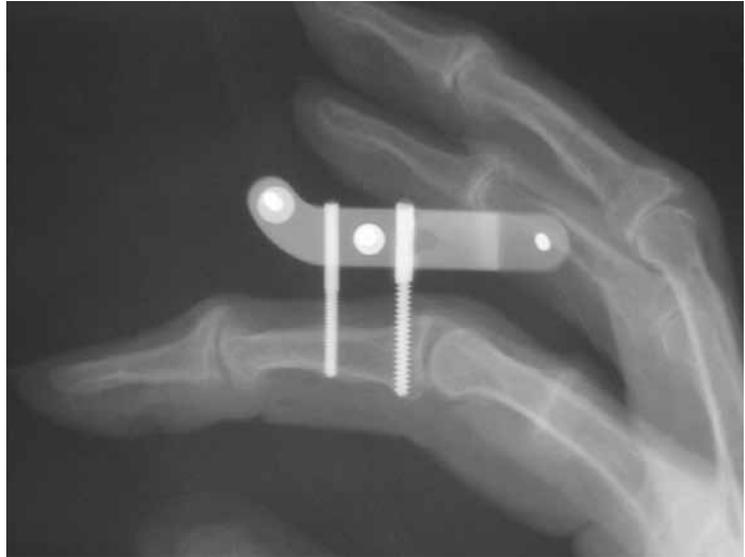


Figure 3

Surgical Installation

Locating Drill Guide

Squeeze the "wings" of the Drill Guide to open the sides enough to place it onto the finger. The metal guide tubes in the rectangular block of the Drill Guide can be visualized on X-ray.

Estimate placement of the proximal Drill Guide tube just distal to the PIP joint space, then use fluoroscopy to ensure the tube is placed distal to the joint. Mark the skin at the proximal end of the guide.

WARNING:

Ensure the marked skin remains positioned relative to the underlying skeleton when using the Drill Guide and Proximal Pre-Drill.

Improper Drill Guide location can result in drilling into the joint space causing damage to the joint surface.

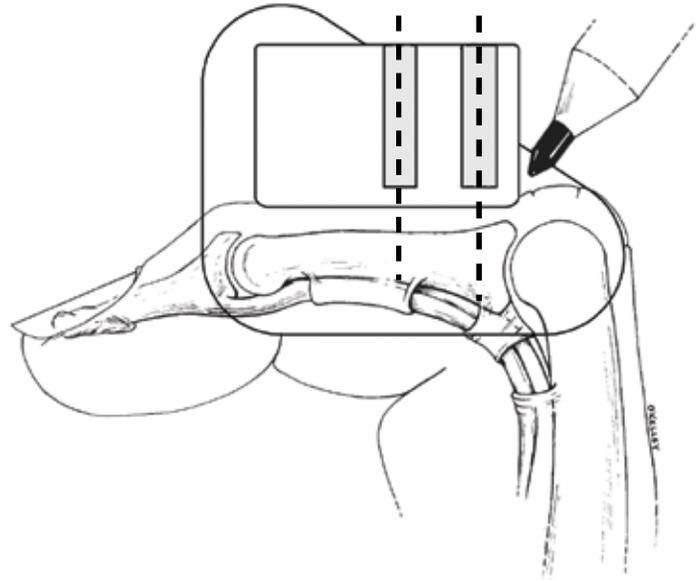


Figure 4

Locating Drill Guide

Center the Drill Guide on the dorsum of the finger so the drill will follow an axis which projects parallel to the proximal phalanx (Fig. 5). Ensure the proximal end of the Drill Guide remains aligned with the skin mark. The goal is to insert the Proximal Pin in the base of the middle phalanx just distal to the subchondral bone (*Inset*).

This Proximal Pin location will...

- 1) Position the device correctly on the finger.
- 2) Reduce the risk of the Distal Pin impairing extensor mechanism gliding.

WARNING:

Avoid inserting the Proximal Pre-Drill into the joint.

Use fluoroscopy to check Drill Guide location prior to drilling the first Pre-Drill. Reposition the Drill Guide if necessary.

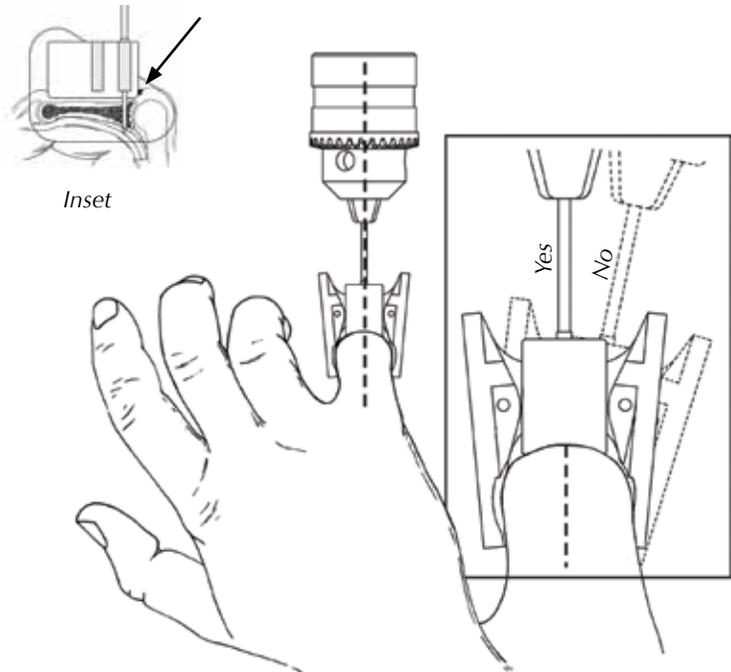


Figure 5

Surgical Installation

Pin Placement: Using Proximal Pre-Drill

Using a power drill, insert the Proximal Pre-Drill through both cortices of the middle phalanx. The Pre-Drill should extend through, but not beyond, the palmar cortex and should not go into the joint space. Disengage the chuck from the Pre-Drill. Do NOT remove the Pre-Drill from the bone.

The surgeon must firmly hold the Drill Guide on the finger while installing the Proximal and Distal Pre-Drills. The Drill Guide's self-clamping mechanism is intended to hold the Guide on the finger during fluoroscopic imaging prior to drilling.

WARNING:

Pin installation should be done under fluoroscopic control.

Careful control of pin location and depth prevents damage to the joint surface and to underlying flexor tendons.

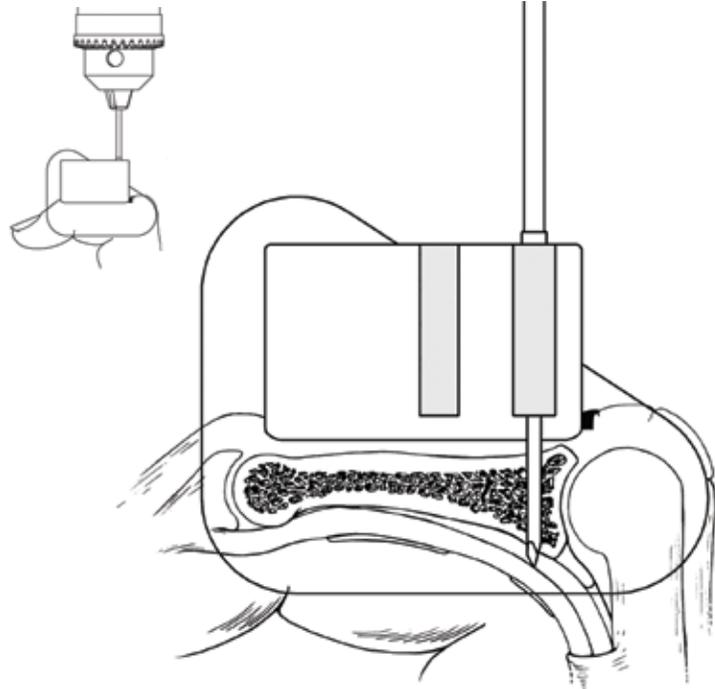


Figure 6

Pin Placement: Using Distal Pre-drill

Using a power drill, insert the Distal 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 Distal Pre-Drill from the bone. Maintain Drill Guide alignment until next step is completed.

CAUTION:

Insert the Distal Pre-Drill into the drill chuck with the chuck depth marker visible (triple lines).

Inserting the Distal Pre-Drill into the chuck beyond the chuck depth marker may cause the chuck to hit the Proximal Pre-Drill while pre-drilling.

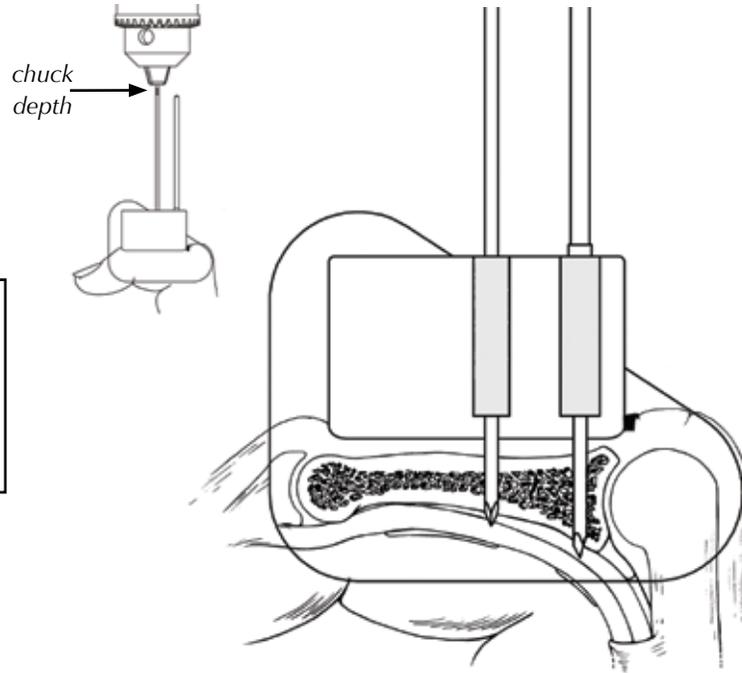


Figure 7

Surgical Installation

Pin Placement: Inserting Distal Pin

Manually insert the Distal Pin by rotating it clockwise into the pre-drilled hole. It should extend through, but not beyond, the palmar cortex of the middle phalanx.

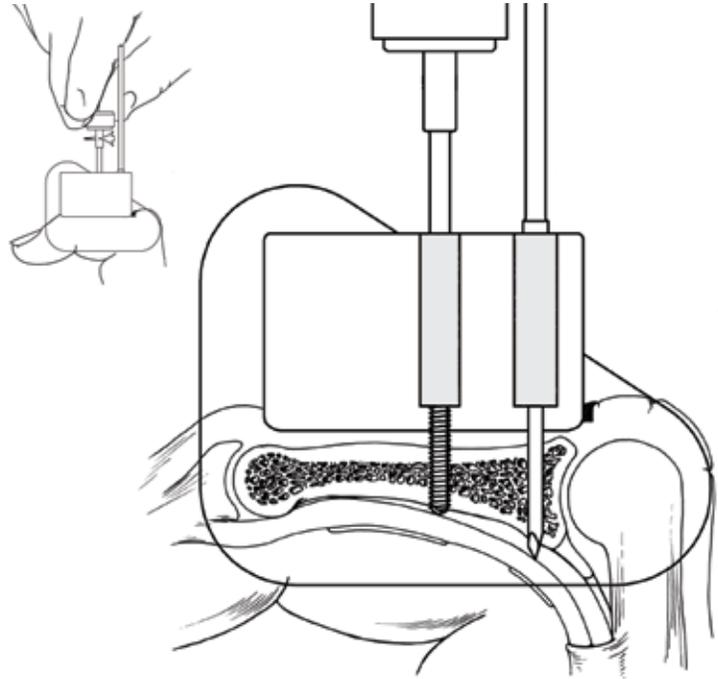


Figure 8

Pin placement: Inserting Proximal Pin

Maintaining alignment of the Drill Guide with the pre-drilled hole, remove the Proximal Pre-Drill from the bone. Manually insert the Proximal Pin by rotating it clockwise into the pre-drilled hole. It should extend through, but not beyond, the palmar cortex of the middle phalanx.

WARNING:

Confirm correct pin depth using fluoroscopy before cutting off pins.

Careful control of pin depth prevents damage to underlying flexor tendons.

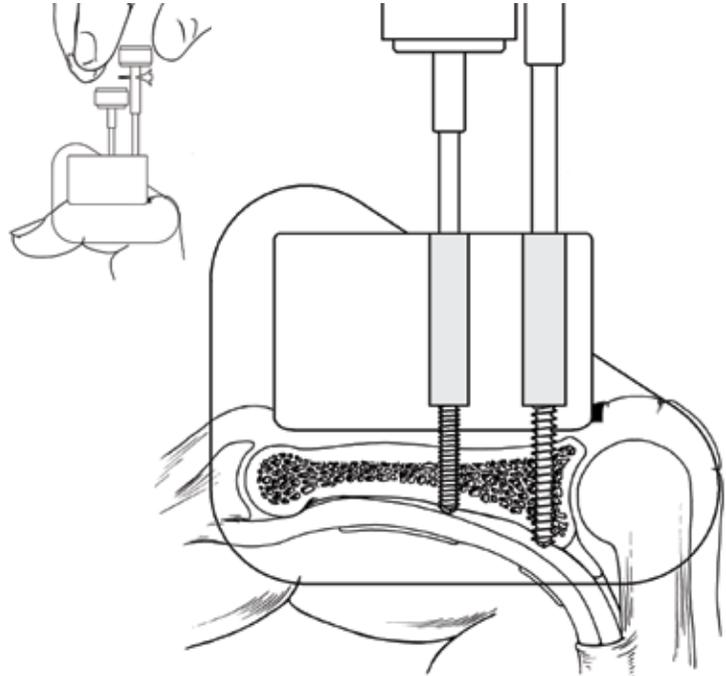


Figure 9

Surgical Installation

Pin Placement: Removing Drill Guide

Make initial pin cuts just below each pin's shoulder to allow Drill Guide removal. The pins must be trimmed to final length only after the next step of installing the Pin Block.

Remove the Drill Guide.

CAUTION:

Cut pins just below the shoulder.

Cutting pins too short may compromise pin security in the Pin Block. Cutting pins above shoulder prevents Drill Guide removal.

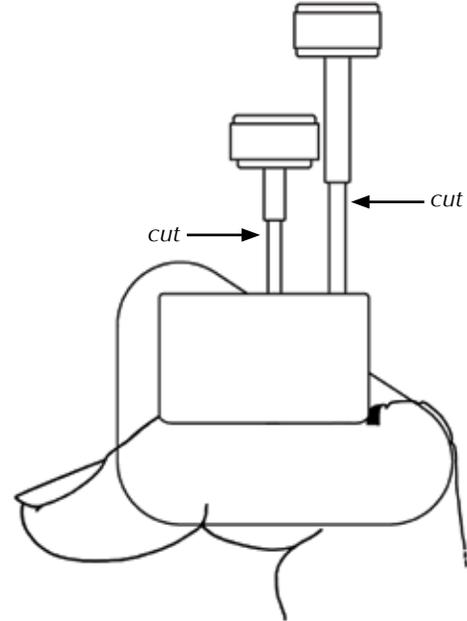


Figure 10

Attaching Pin Block

Use the Hex Wrench to loosen the pin clamp screw a couple turns to open the pin clamp. Slide the Pin Block over the pins until it is approximately 3/16" (5 mm) above the dorsal skin to allow for finger swelling. Tighten the pin clamp screw. Cut off the pins so that they are flush with the top of the Pin Block.

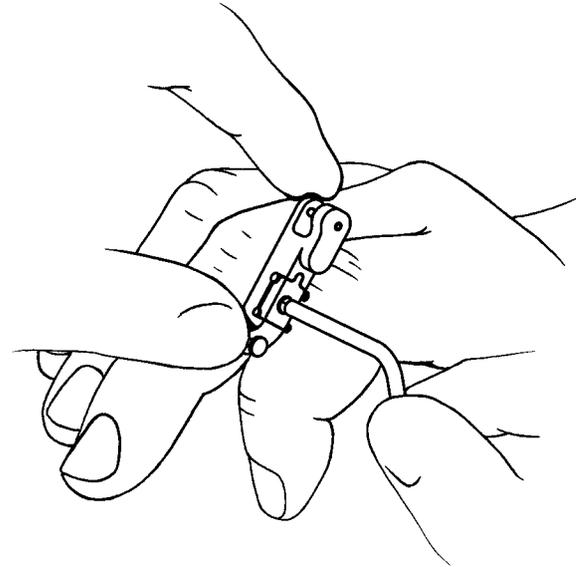


Figure 11



Post-Surgery Assembly

The following section covers the portion of device application to be completed after surgery. The Digit Widget components described in this section should not be sterilized and are contained in Pack B.

Two different size Cuffs are provided to accommodate most adult hands with or without additional surgical dressing. The Cuffs are designed to fit both right and left hands.

Note, at the surgeon's discretion, the components used in this section can be removed and reapplied by the patient to facilitate hand washing.

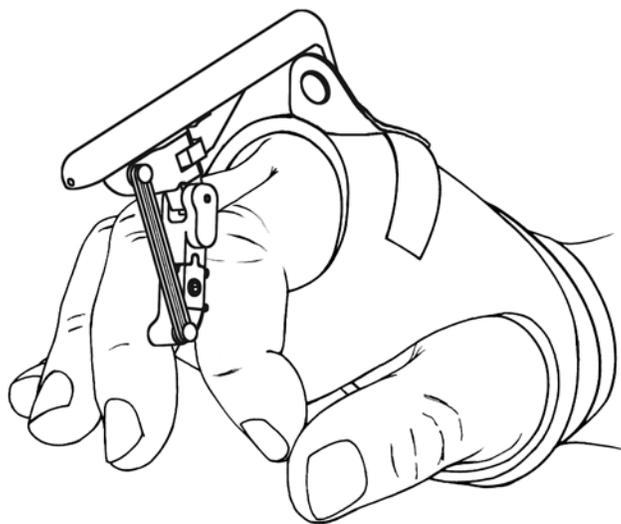


Figure 12: Installed Digit Widget

Post-Surgery Assembly

Fitting Cuff

Two different size Cuffs are included to accommodate most adult hands with or without additional surgical dressing. You may wish to experiment to find the most comfortable fit. The remaining Cuff should be saved in case it is needed later. Each Cuff fits both right and left hands.

Position the unwrapped Cuff on the hand as shown with the smoother side against the skin (*Inset*).

Wrap the finger strap across the palm and attach **near the wrist**. Position the Cuff's distal edge **parallel** to the base of the fingers.

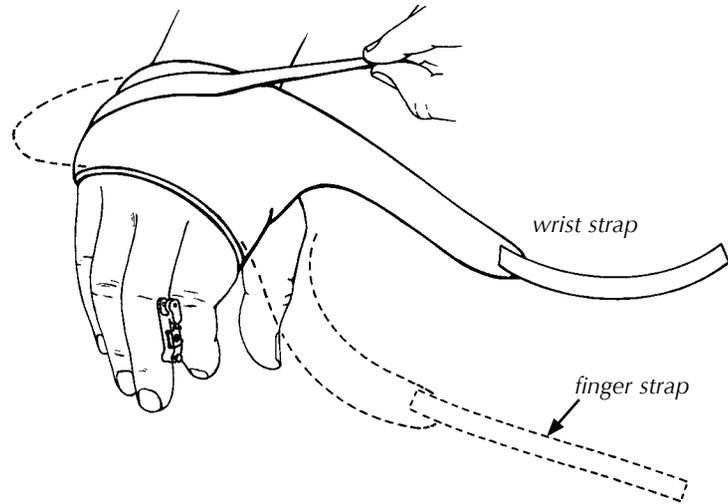
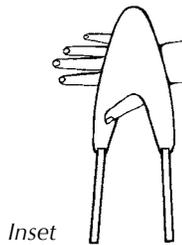
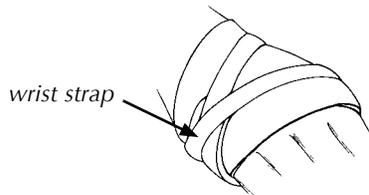


Figure 13

Post-Surgery Assembly

Fitting Cuff

Wrap the wrist strap across the palm and attach starting near the base of the small finger and continuing to the thumb-index web space. Properly secured straps should form an X or V pattern when viewed from the back of the hand (*Inset*). Secure the Cuff snug enough to prevent movement on the hand but not so tight as to cause discomfort or distal edema. The straps may be trimmed to length.



Inset

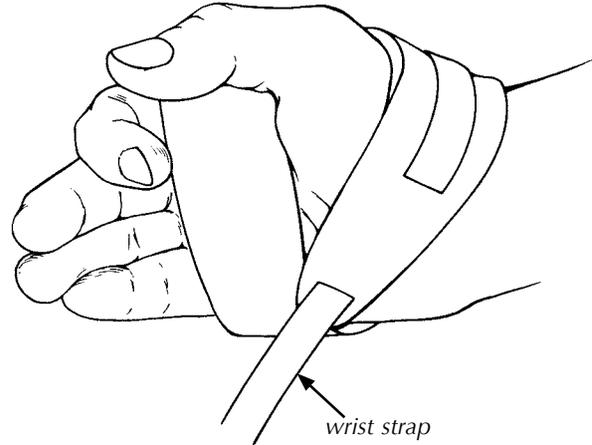


Figure 14

Attaching Connector Assembly

Snap the Connector Assembly onto the Pin Block pivot as shown. Support the Pin Block while attaching the Connector Assembly to isolate the Bone Pins and finger from the snapping force. Assistance may be required.

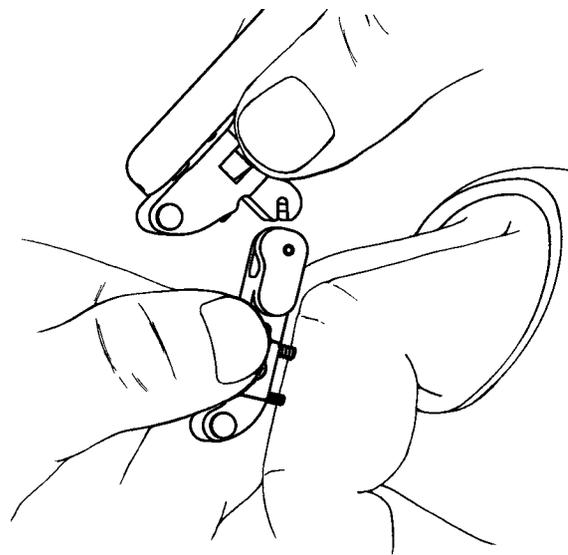


Figure 15

Post-Surgery Assembly

Attaching Connector Assembly

Attach the Connector Assembly to the Cuff by means of the hook and loop tab. The tab should be centered over the involved finger's metacarpophalangeal joint.



Figure 16

If, after the Elastic Bands are installed (see next page), the hook and loop tab is lifting the Cuff away from the hand, the tab may be placed onto the Cuff first and the wrist strap wrapped over it.

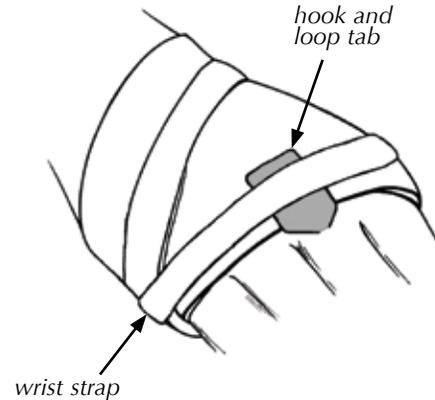


Figure 17

Fitting Elastic Bands

Initiate a torque by installing an Elastic Band on the posts. Extension torque is dependent on the strength of the Elastic Band(s) used. In general, start with a single light strength band applying continuous torque. If joint extension does not improve, change to a medium or heavy band. Multiple bands can also be used.

Excessive torque should be avoided and is typically accompanied by pain, swelling, inflammation and loss of joint range of motion. The goal of treatment is to use the least torque which improves joint extension. A low torque applied for a long period is preferable to a short period of high torque.

WARNING:

The Elastic Bands contain natural rubber latex which may cause allergic reactions.

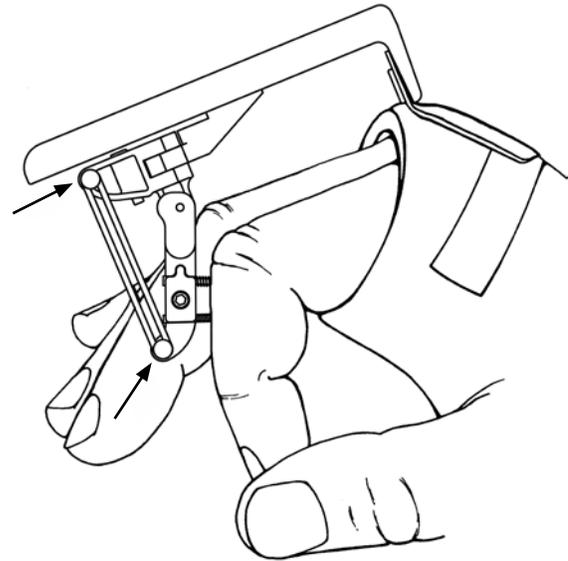


Figure 18

Post-Surgery Assembly

Adjusting Extension Stop

To prevent hyperextension when the PIP joint reaches full extension, adjust the extension stop screw using the supplied 5/64" Hex Wrench.

When the joint begins to reach full extension, evaluate the extension stop position to determine if adjustment is required. Evaluation should be performed with Elastic Band(s) in place. Access to the adjustment screw is obtained by disconnecting the hook and loop tab from the Cuff and sliding the Connector Assembly proximally. Adjust the extension stop the desired amount and then reattach the tab to the Cuff. After reattaching the tab, check to ensure the adjusted extension stop prevents hyperextension while still maintaining the device's performance at joint angles less than full extension.

WARNING:

Ensure extension stop screw does not interfere with Connector Assembly.

Unscrewing the extension stop beyond its range of adjustment may cause the screw to interfere with Connector Assembly function.

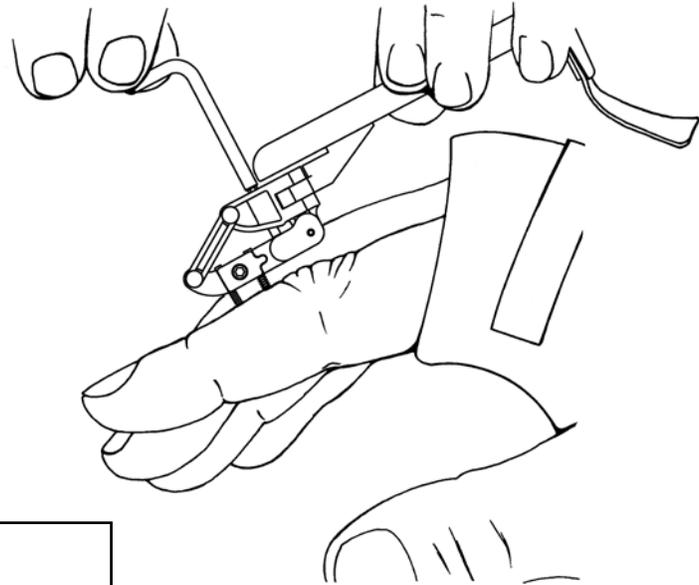


Figure 19

Fine Tuning Connector Assembly Location

As the PIP joint reaches full extension, the pivot block retracts along the connector rail. On small hands, this may result in the Connector Assembly hood overhanging the fingertip, creating a potential clothing snag.

If you wish to reduce the length of Connector Assembly overhang, reposition the hook and loop tab slightly proximally on the Cuff. After repositioning, ensure the device does not restrict MP or PIP flexion.

Positioning the hook and loop tab proximal to the MP joint will result in the MP joint being subjected to a small extension force. Unless the distance is great, this force will be small and clinically insignificant.

Post-Surgery Assembly

Controlling MP Joint Hyperextension

Some patients with PIP flexion contractures also hyperextend at their MP joints (*Fig. 20*). To prevent this, an MP Flexion Strap (shaded) is included in Pack B.

If indicated, place the MP Flexion Strap, pad side down, over the top of the involved finger as shown. Flex the MP joint as the hook and loop straps are securely attached to the palm side of the Cuff (*Fig. 21*). The straps and pad may be trimmed as needed.

With the strap in place, the MP joint does not hyperextend. This allows for more effective transmission of the extension torque to the PIP joint (*Fig. 22*).

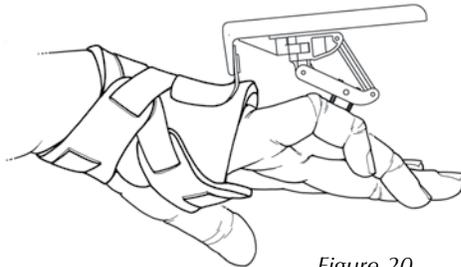


Figure 20

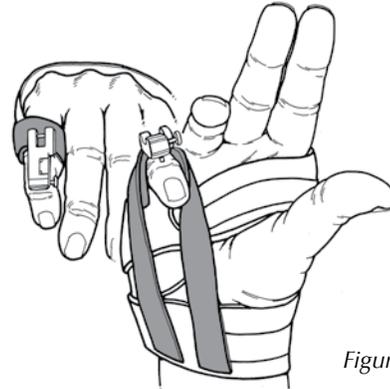


Figure 21

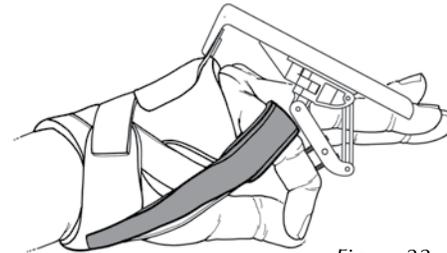


Figure 22

Clinical Course and Fixator Removal

Device and Pin Track Care

The device should be kept free of foreign bodies and substances such as hand lotion, blood, or antibacterial ointments.

The patient should be instructed in pin track care using the surgeon's method of choice. Liquid antibacterial soap and water will not interfere with the function of the device.

Fixator Removal

The Cuff and Connector Assembly may be removed for hand washing and/or showering. First remove the Elastic Band(s), disengage the Connector Assembly from the Cuff and Pin Block then remove the Cuff.

For complete device removal, perform the above steps, then use the 5/64" Hex Wrench to loosen the pin clamp screw. Unclamp the Pin Block from the pins and manually remove the pins from the bone using a needle holder.