



## PRODUCT DESCRIPTION

The Paragon 28® Monkey Bars™ External Fixation System allows for a wide variety of constructs. Pin placement and construct type depends on the injury or condition being addressed. Pins used with a number of Combination Clamps, Multi-Pin Clamps and Bars is all left to individual surgeon discretion.

## CONTENTS

<b>Section 1</b>	<b>MONKEY BARS™ PIN-TO-BAR EXTERNAL FIXATOR</b>
	<b>SYSTEM COMPONENTS AND FEATURES..... 3-4</b>
	<b>FRAME BUILDING GUIDELINES.....5</b>
<b>Section 2</b>	<b>REPAIR TECHNIQUE</b>
	<b>DISTAL TIBIA FRACTURE..... 5-9</b>
	<b>MID-SHAFT TIBIA FRACTURE .....10-14</b>
<b>Section 3</b>	
	<b>CADDY LAYOUT ..... 15</b>
	<b>INDICATIONS, CONTRAINDICATIONS, WARNINGS..... 16-17</b>

# SYSTEM COMPONENTS AND FEATURES



Calibrated Step Drill



**Half Pins:**


















Self Drilling/Self-Tapping, or Blunt Tipped 3 mm 4 mm and 5 mm stainless steel Pins produced in a variety of thread and Pin lengths. Both partially threaded Half Pins.

**Transfixation Pin:**

A centrally threaded Transfixation Pin is available.



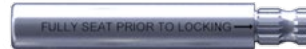
5 mm Pin Cap

	Calibrated Step Drill Size	Thread Tip	Overall Length	Thread Length	Diameter
Half Pin Size	2.4 mm x 140 mm 	Self Tapping 	150 mm	20 mm	3 mm
		Blunt 	150 mm	20 mm	3 mm
	3.2 mm x 165 mm 	Self Tapping 	150 mm	20 mm	4 mm
		Blunt 	150 mm	20 mm	4 mm
		Self Tapping 	150 mm	30 mm	4 mm
		Blunt 	150 mm	30 mm	4 mm
	4.0 mm x 200 mm 	Self Tapping 	150 mm	35 mm	5 mm
		Blunt 	150 mm	35 mm	5 mm
		Self Tapping 	150 mm	45 mm	5 mm
		Blunt 	150 mm	45 mm	5 mm
		Self Tapping 	200 mm	55 mm	5 mm
		Blunt 	200 mm	55 mm	5 mm
Self Tapping 		200 mm	65 mm	5 mm	
Blunt 		200 mm	65 mm	5 mm	

# SYSTEM COMPONENTS AND FEATURES



**Combination Clamp:**  
Combination Clamps allow for Pin-to-Bar and Bar-to-Bar fixation with 360 degrees of freedom.



Straight

**Posts:**  
0 degree Straight and 30 degree Angled posts for multiple Pin Clamps to provide construct versatility



Angled



8 Hole Pin Clamp

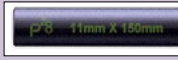
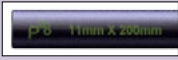
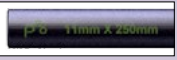







5 Hole Pin Clamp

**Multiple Pin Clamps:**  
5 hole and/or 8 hole Clamps to ease construct creation and stability.



**Bars:**  
Carbon fiber 11 mm diameter Bars. Length range 150 mm to 500 mm

Bar Sizes							
150 mm		200 mm		250 mm		300 mm	
350 mm		400 mm		450 mm		500 mm	



Tissue Protector with Handle



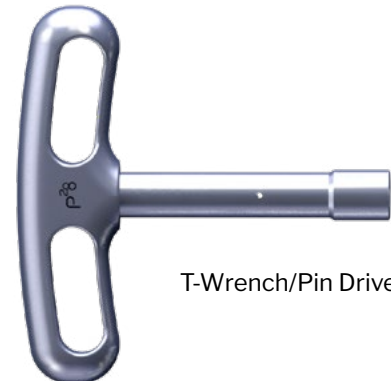
Tissue Protector Sleeve



Trocar



10 mm Wrench



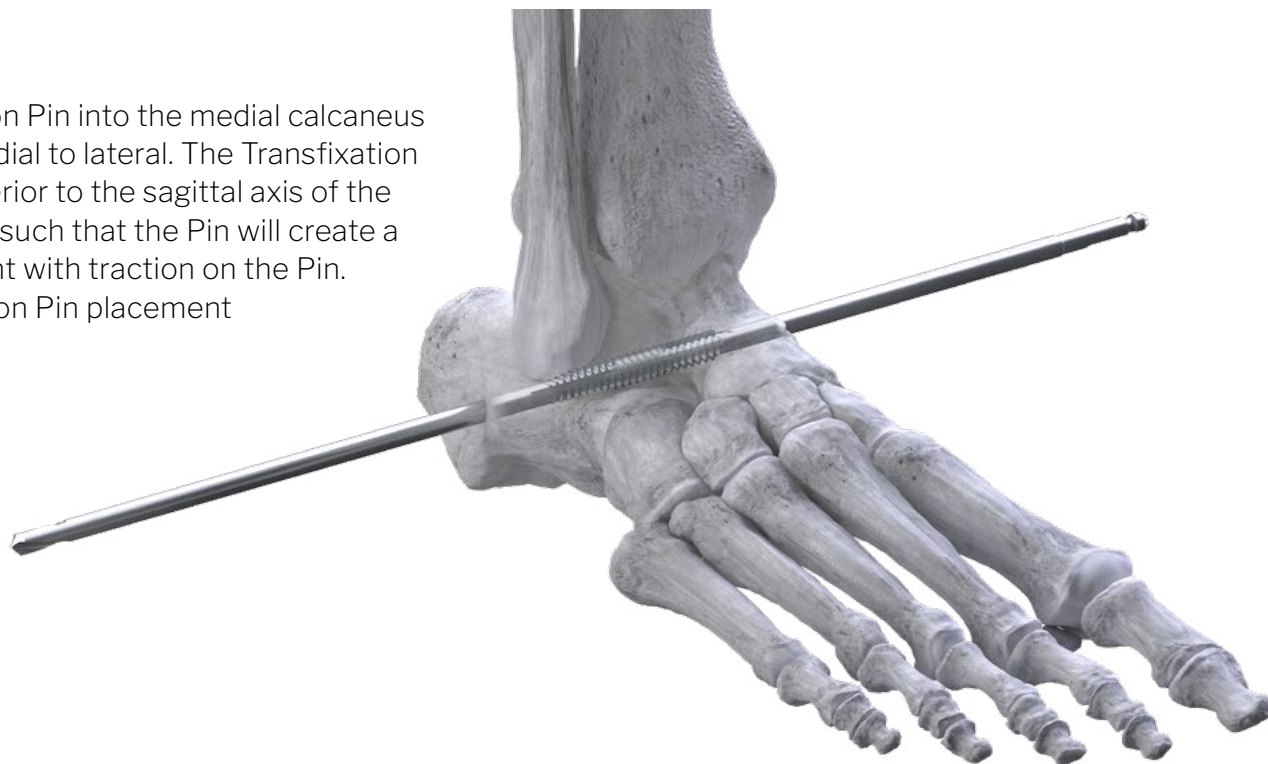
T-Wrench/Pin Driver

## FRAME BUILDING GUIDELINES

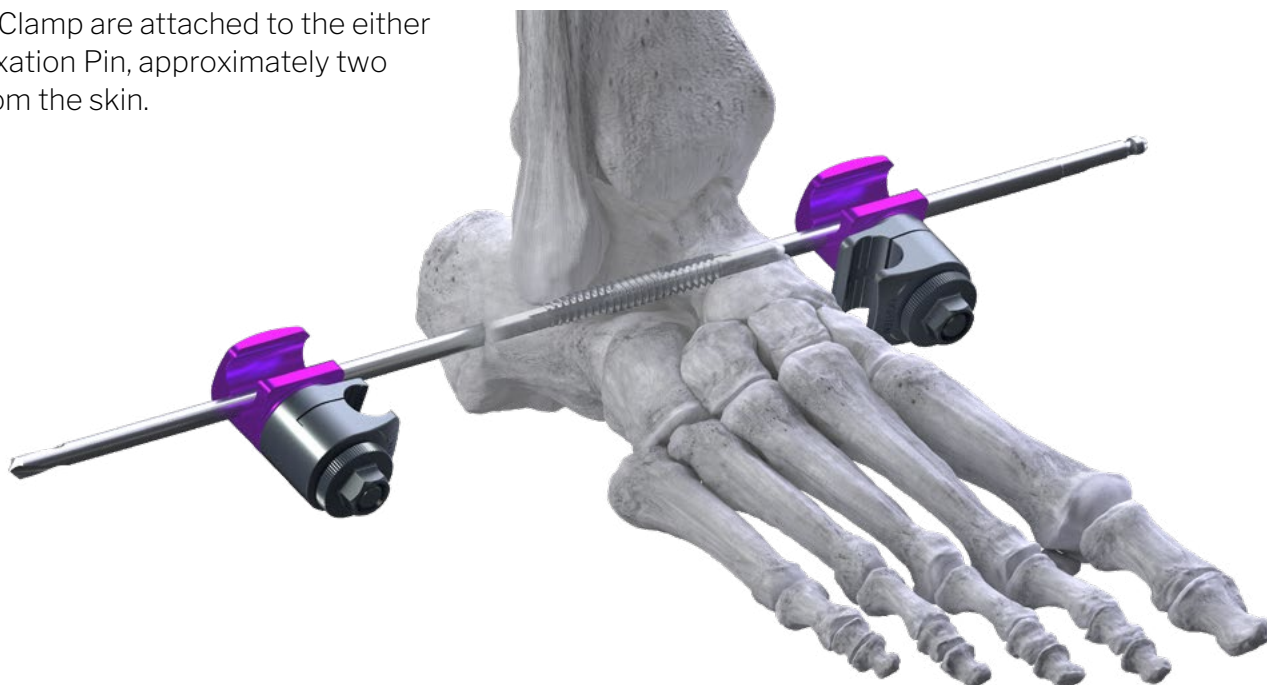
The principles described in this technique are applicable to a variety of applications. Although many construct types can be created, basic principles of external fixation should be followed. Avoid placing Pins in the zone of injury. Place all Clamps and Bars at least two centimeters above soft tissue to allow for swelling and dressing placement. Construct stability is increased by increasing Pin spread, increasing number of Pins, decreased bone to Bar distance, in-line Bar stacking, utilization of multiple Pin Clamps and 90° side Bar utilization.

## DISTAL TIBIA FRACTURE

Insert a Transfixation Pin into the medial calcaneus safe zone, from medial to lateral. The Transfixation Pin should be posterior to the sagittal axis of the ankle and hindfoot, such that the Pin will create a dorsiflexion moment with traction on the Pin. Confirm Transfixation Pin placement using fluoroscopy.



Two Combination Clamp are attached to the either side of the Transfixation Pin, approximately two finger breadths from the skin.





# DISTAL TIBIA FRACTURE

For the placement of the most proximal Pin, make a stab incision over the anticipated Pin placement. Use blunt dissection through the soft tissue to bone, using a Trocar if desired. Place either a Tissue Protector Sleeve and/or Tissue Protector with Handle against the tibial bone.



**NOTE:** Alternatively, the 8 Hole Pin Clamp may be used, per surgeon preference. Though it is recommended to place Half Pins through the outer most holes of the Clamps, a combination of any holes may be used, per surgeon preference and based on patient needs.



**NOTE:** There are two options for Half Pins available in the system, Self Tapping and Blunt Tipped. In the proximal tibia where dense bone is typically encountered, it is recommended to drill using the provided Drills corresponding to Half Pin diameter prior to Half Pin placement (refer to page 3).

Make a stab incision over the anticipated Pin placement. Use blunt dissection through the soft tissue to bone. If desired, a Trocar can be placed through the tissue protector to allow for separation of the soft tissue before Pin placement.



Drill using the corresponding Drill for the anticipated Half Pin diameter. Drilling through the first Tissue Protector can be performed uni- or bi-cortically, based on anatomic location and surgeon preference.



Remove the Drill and insert the selected Half Pin in the tibia. The Half Pin can be inserted under power, with final insertion completed with the T-Wrench/Pin Driver. Remove the Tissue Protector. Retrieve a 5 Hole Pin Clamp and place over the Half Pin through the proximal hole of the Pin Clamp.

# DISTAL TIBIA FRACTURE



Insert a Tissue Protector into the 5 Hole Pin Clamp, on the opposite side of the first Half Pin. Make a stab incision over the anticipated Pin placement. Use blunt dissection through the soft tissue to bone, using a Trocar if desired. Drill (uni- or bi-cortically) through the Tissue Protector using the corresponding Drill for the anticipated Half Pin diameter.



Remove the Drill and repeat the steps for Half Pin Insertion. Hand tighten the nuts on the side of the 5 Hole Pin Clamp.



Attach two 30° Angled Posts to each side of the 5 Hole Pin Clamp, angling the Posts posteriorly. Align the laser marked arrows on the posts to one another to ensure both posts are placed at the same relative position. Tighten the nuts on the top of the 5 Hole Pin Clamp by rotating clockwise to secure the Angled Posts.

**NOTE:** Posts should be fully seated prior to tightening.

Seated

Not Seated

# DISTAL TIBIA FRACTURE

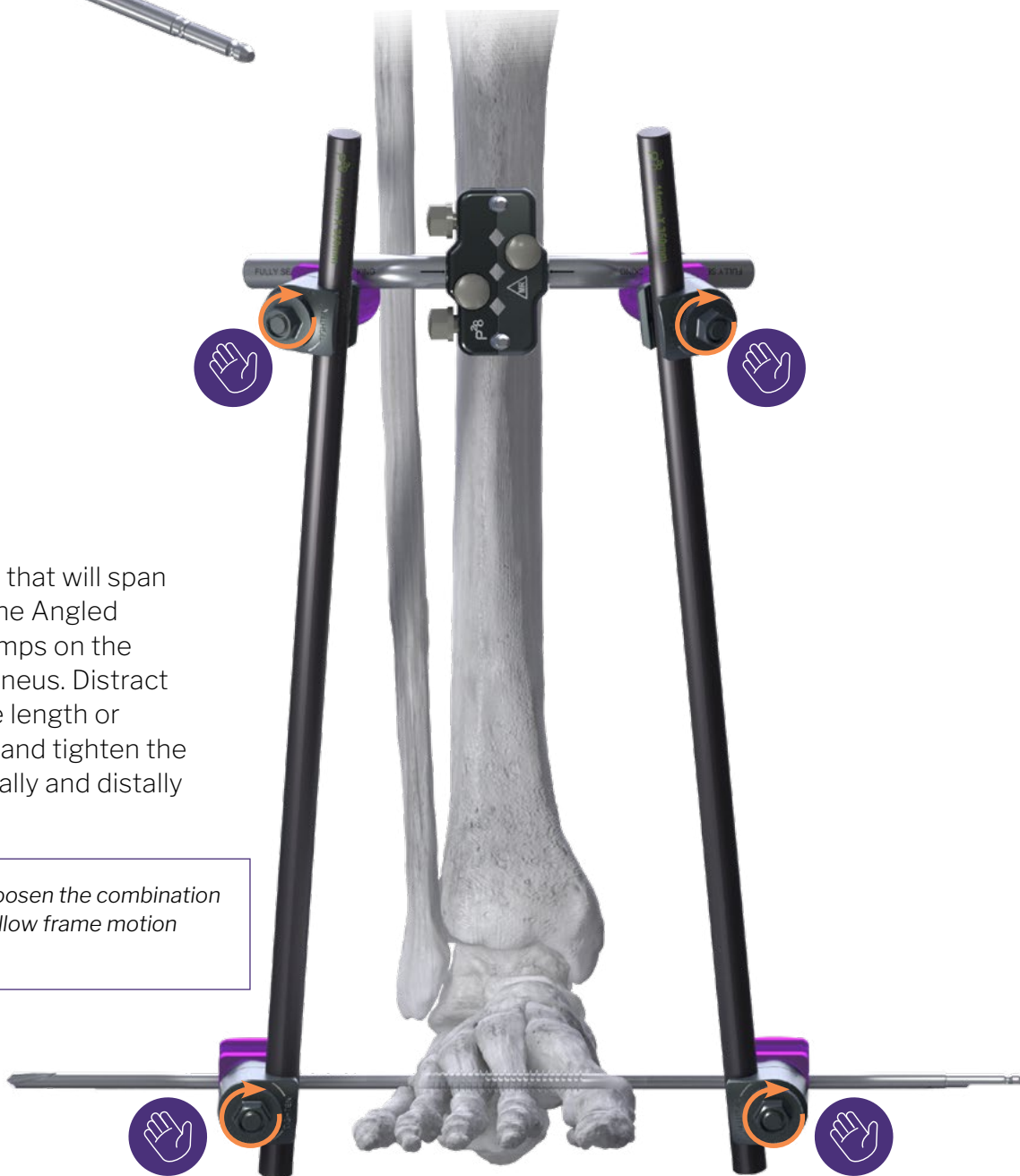
Retrieve two Combination Clamps, and place one on each of the Angled Posts, aligned such that the Angled Posts snap into the purple portion of the Combination Clamp and the nut is anterior.



Retrieve two Bars, in lengths that will span the Combination Clamp on the Angled Post to the Combination Clamps on the Transfixation Pin in the calcaneus. Distract the fracture until appropriate length or reduction is achieved, then hand tighten the Combination Clamps proximally and distally to hold the Bars in position.



**NOTE:** User may need to loosen the combination clamp nut 1 revolution to allow frame motion during the reduction.





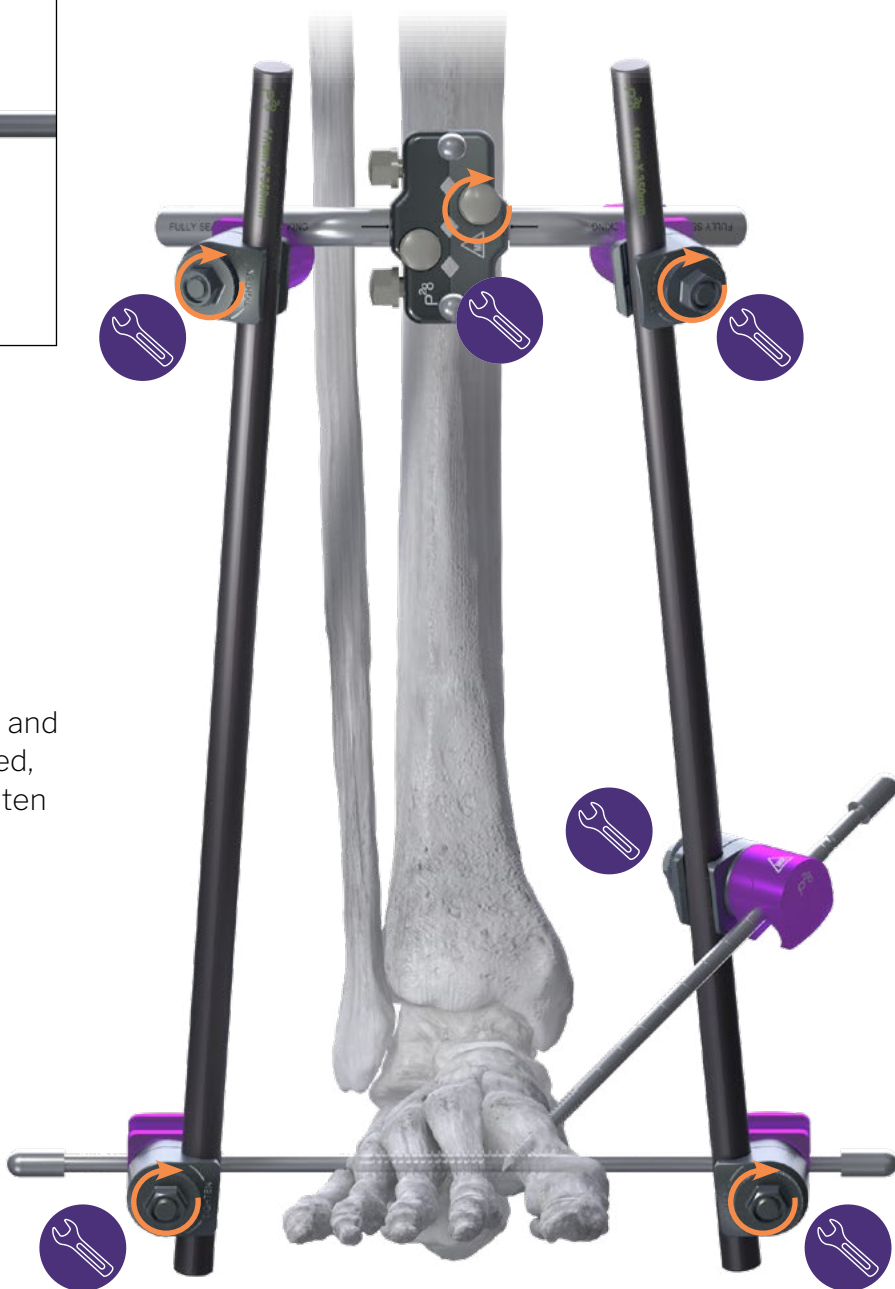
# DISTAL TIBIA FRACTURE



For additional stability of the foot, a Half Pin can be inserted into the 1<sup>st</sup> metatarsal. Retrieve the desired Half Pin diameter and insert the Half Pin into the base of the first metatarsal at the anterior medial portion to avoid the extensor tendons.

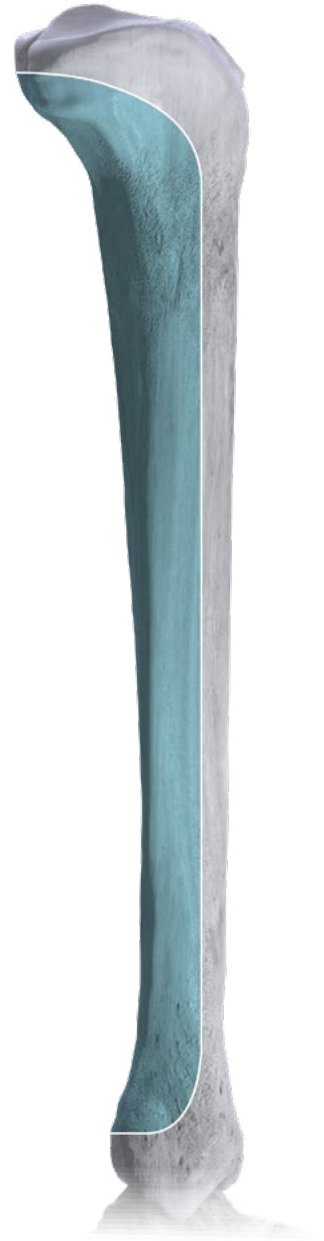
The proximal end should terminate near the medial Bar. Attach a Combination Clamp such that the gray portion (nut posterior) snaps onto the Bar and the purple portion snaps onto the Pin. Hand tighten the Combination Clamp to secure to the Bar.

Confirm appropriate fracture length/reduction and foot position using fluoroscopy. Once confirmed, use the Wrench or T-Wrench/Pin Driver to tighten all nuts in the construct.



## MID-SHAFT TIBIA FRACTURE

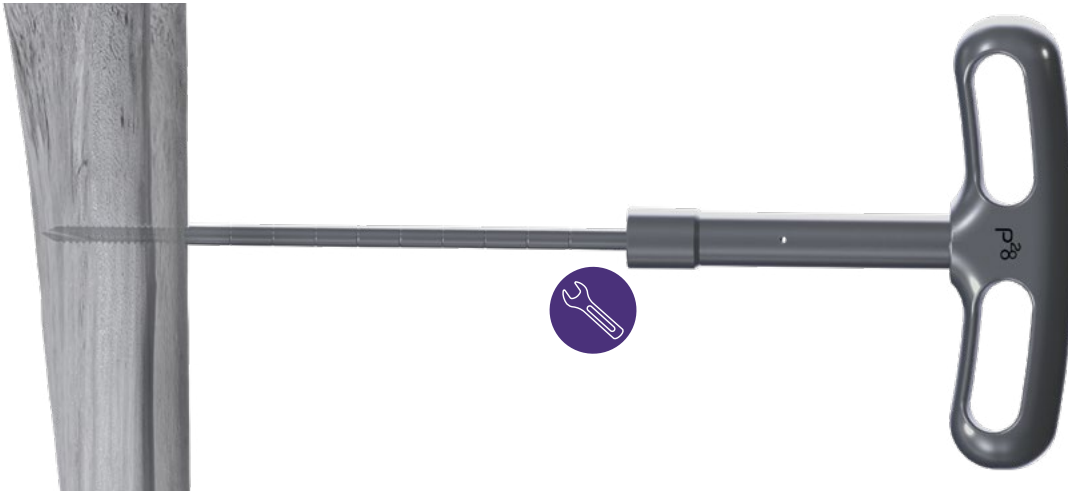
Half Pin insertion into the tibia should be on the medial side, in the safe zone.  
Half Pins are recommended to be placed 15°-20° angled from the coronal plane.



Make a stab incision over the anticipated proximal Half Pin placement, such that the 5 Hole Pin Clamp will be located at least 2 cm above the fracture site. Use blunt dissection through the soft tissue to bone. Retrieve a Tissue Protector Handle and place against bone over the anticipated proximal Half Pin location. If desired, a Trocar can be placed through the Tissue Protector to allow for separation of the soft tissue before Pin placement. Drill using the corresponding Drill for the anticipated Half Pin diameter. Drilling can be performed uni- or bi-cortically, based on anatomic location and surgeon preference, through the first Tissue Protector

# MID-SHAFT TIBIA FRACTURE

Remove the Drill and insert the selected Half Pin in the tibia. The Half Pin can be inserted by hand or under power, with final insertion completed with the T-Wrench/Pin Driver.



Retrieve a 5 Hole Pin Clamp and place the Half Pin through the proximal hole in the Pin Clamp. Place either a Tissue Protector Sleeve and/or Tissue Protector with Handle through the distal hole of the 5 Hole Pin Clamp, opposite the first Half Pin.



Make a stab incision over the anticipated Pin placement. Use blunt dissection through the soft tissue to bone, using a Trocar if desired. Drill (uni- or bi-cortically) through the Tissue Protector using the corresponding Drill for the anticipated Half Pin diameter.

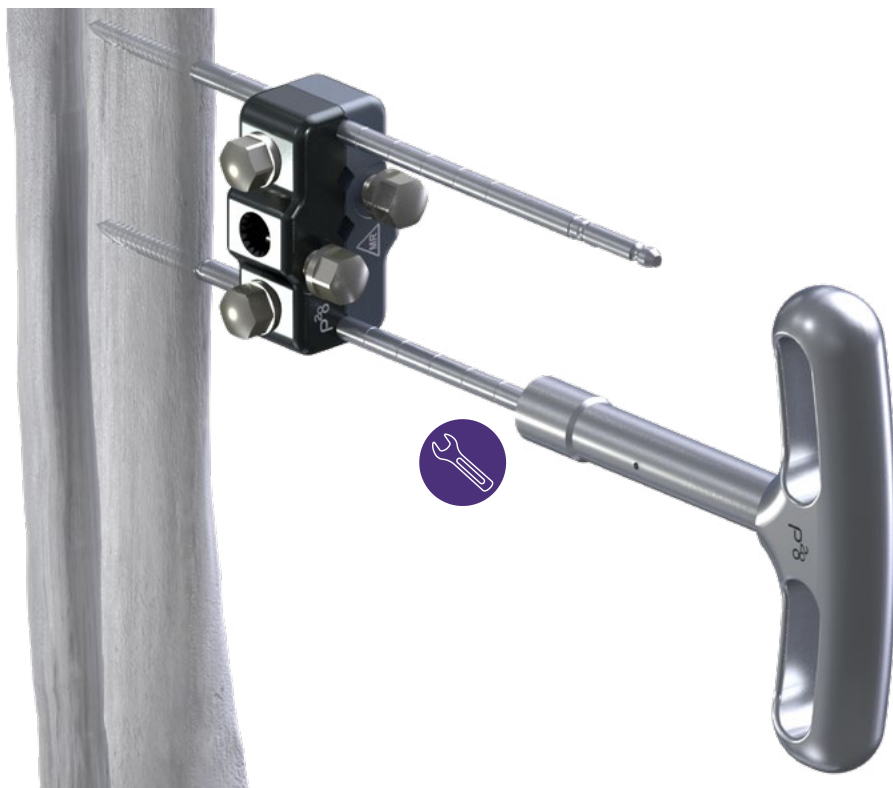


**NOTE:** Alternatively, the 8 Hole Pin Clamp may be used, per surgeon preference. Though it is recommended to place Half Pins through the outer most holes of the Clamps, a combination of any holes may be used, per surgeon preference and based on patient needs.



**NOTE:** There are two options for Half Pins available in the system, Self Tapping and Blunt Tipped. In the proximal tibia where dense bone is typically encountered, it is recommended to drill using the provided Drills corresponding to Half Pin diameter prior to Half Pin placement (refer to page 3).

## MID-SHAFT TIBIA FRACTURE

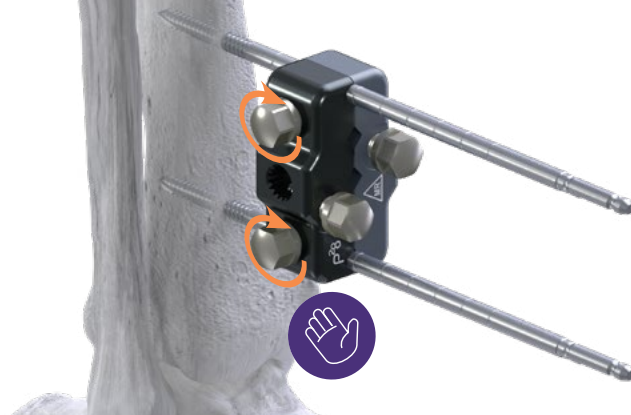


Remove the Drill and repeat the steps for Half Pin Insertion.

Position the 5 Hole Pin Clamp about 2 finger breadths away from the skin. Hand tighten the nuts on the side of the 5 Hole Pin Clamp.



Repeat the steps for placing the Half Pins and 5 Hole Pin Clamp for the distal 5 Hole Pin Clamp.





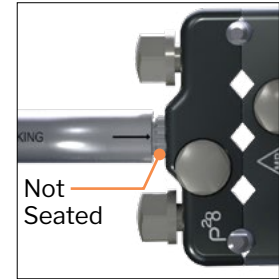
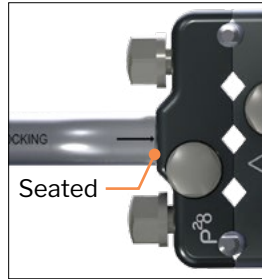
# MID-SHAFT TIBIA FRACTURE



Attach two 30° Angled Posts to each side of each 5 Hole Pin Clamp, angling the Posts posteriorly. Align the laser marked arrows on the posts to one another to ensure both posts are placed at the same relative position. Tighten the nuts on the top of the 5 Hole Pin Clamp by rotating clockwise to secure the Angled Posts.



**NOTE:** Posts should be fully seated prior to tightening.



Retrieve four Combination Clamps, and place one on each of the Angled Posts, aligned such that the Angled Posts snap into the purple portion of the Combination Clamp and the nut is anterior.



## MID-SHAFT TIBIA FRACTURE



Retrieve two Bars, in lengths that will span the Combination Clamps on the distal and proximal Angled Posts on the medial and lateral sides. Distract the fracture until appropriate length or reduction is achieved, then hand tighten the Combination Clamps proximally and distally to hold the Bars in position.



**NOTE:** User may need to loosen the combination clamp nut 1 revolution to allow frame motion during the reduction.

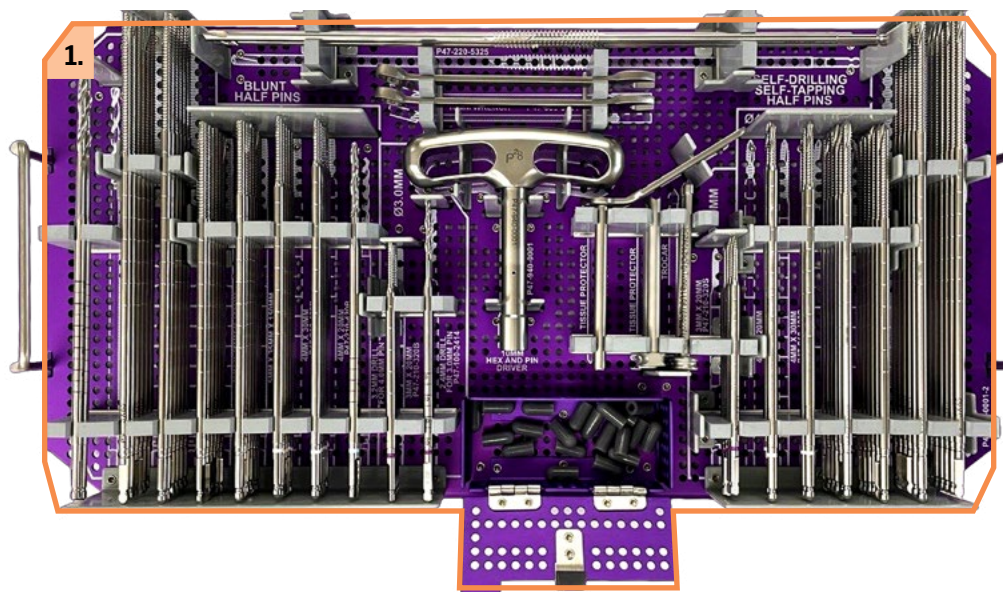


Confirm appropriate fracture length/reduction and foot position using fluoroscopy. Once confirmed, use the Wrench or T-Wrench/Pin Driver to tighten all nuts in the construct.

# MONKEY BARS® EXTERNAL FIXATION CADDY AND CASE

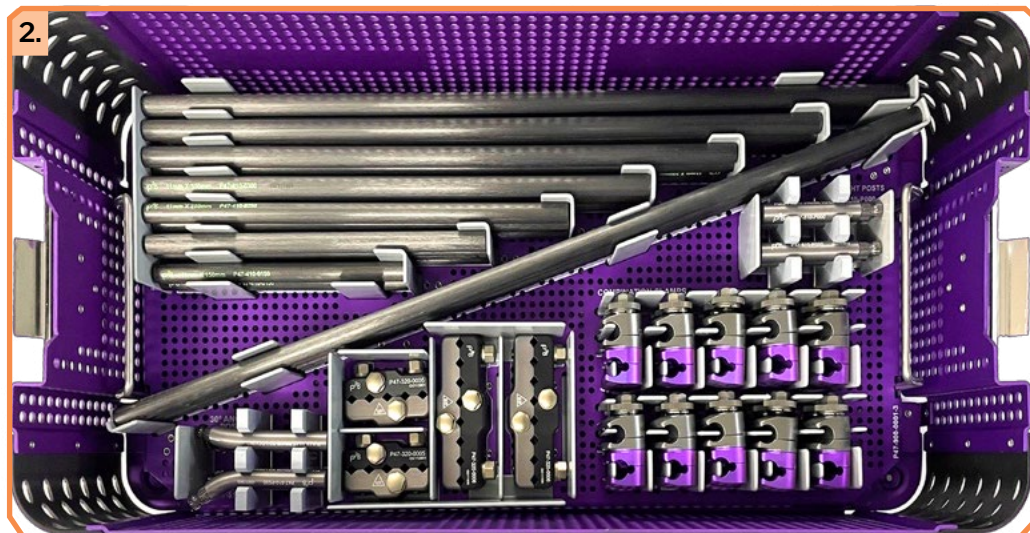
## 1. MONKEY BARS™ CADDY

The Monkey Bars™ External Fixation System instrument Caddy contains Calibrated Step Drills, Transfixation Pin, Half Pins, Trocar, Tissue Protector Sleeve, Tissue Protector with Handle, 100 mm Wrench, T-Wrench/Pin Driver and 5 mm Pin Caps.



## 2. MONKEY BARS™ CASE

The Monkey Bars™ External Fixation System Case contains Bars, 5 and 8 Hole Multiple Pin Clamps, Posts (angled and 30 degree) and Combination Clamps.



Refer to [www.paragon28.com/ifus](http://www.paragon28.com/ifus) for the complete and most current instructions for use document.

## INDICATIONS FOR USE

The Monkey Bars™ Pin to Bar External Fixation System is intended to be used in adult and pediatric patients for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.

## CONTRAINDICATIONS

- Mental conditions that preclude cooperation with the rehabilitation regimen.
- Patients with bone conditions or fracture patterns that prevent secure implantation of multiple pins in the coronal plane.
- Patients with metal allergy

## WARNINGS

- The bone should be drilled slowly so that heat buildup does not cause tissue or bone necrosis.
- Pin placement should avoid locations that will lead to damage to muscles, tendons, vessels or nerves.
- Use care when handling sharp pin, trocar and drill tips.

## PREOPERATIVE PLANNING

**1. Surgical Technique.** Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants. Please review the surgical technique for effective surgical procedures.

**2. Implant and External Component Selection.** Proper type and size of implants and components must be selected to insure effective treatment of patients. The following factors should be considered:

- A patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the device.
- A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
- Whether a patient has a degenerative or progressive disease that delays or prevents healing and leads to exceeding the effective life of the device.
- If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.

- Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

**3. Device Alterations.** The ends of the pins protruding beyond the clamps after the system is assembled may be cut to reduce excess length. Hold the end of the pin when cutting. Cover the protruding ends of the pins with pin caps. Other than cutting the ends of the pins, the components are not designed to be physically altered, bent, notched, gouged, reamed, scratched or cut.

**4. Component Compatibility.** Components such as clamps, rods, pins and posts are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Do not mix components from different manufacturers.

**5. Implant Removal.** The patient should be advised that a second procedure for the removal of implants will be necessary.

## POSTOPERATIVE CARE

After completion of procedure all pin sites should be inspected to ensure there is no skin tenting or soft tissue impingement. Sterile dressings can be placed around pins to prevent bleeding or hematoma formation. We recommend daily cleaning with soap and water, chlorhexidine or alcohol.

**Care Prior to Bony Union:** Postoperative follow-ups and radiographs are recommended. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact and should not be considered for patients who are obese and/or noncompliant, as well as patients who could be predisposed to delayed or non-union. Patients and nursing care providers should be advised of these risks.

**Care Subsequent to Bony Union:** Even after bony union, the patient should be cautioned that a fracture is more likely with the device in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the voids left after removal of the pins.

Refer to [www.paragon28.com/ifus](http://www.paragon28.com/ifus) for the complete and most current instructions for use document.

Implant Removal. The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. After bone healing is observed, the device serves no purpose and must be removed. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

### MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the External Fixation System is MR Conditional for use external to the scanner bore. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 1,180 G/cm (11.8 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg.
- Implant should be located outside the scanner bore.

**RF heating** -Under the scan conditions defined above, the External Fixation System is expected to produce a maximum temperature rise of less than 1 °C after 15 minutes of continuous scanning.

**MR Artifact** -In non-clinical testing, the image artifact caused by the device is not detectable when the External Fixation System is located outside the scanner bore.

### NO REUSE

Surgical implants and components are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation or use. Single use devices should not be reused due to risks of breakage, failure or patient infection.

### POSSIBLE ADVERSE EFFECTS

- Loosening, bending, cracking or fracture of the implant or components.
- Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
- Infections, both deep and superficial.
- Irritational injury of soft tissues, including impingement syndrome.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
- Metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.







# MONKEY BARS™

## PIN TO BAR EXTERNAL FIXATION SYSTEM

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Distributed by:  
Paragon 28®, Inc.  
14445 Grasslands Dr.  
Englewood CO, 80112 USA  
(855) 786-2828  
[www.paragon28.com](http://www.paragon28.com)

Manufactured by:  
The Orthopaedic Implant Company  
316 California Ave #701  
Reno, NV 89509  
(800) 619-2797  
[www.orthoimplantcompany.com](http://www.orthoimplantcompany.com)

### DISCLAIMER

The purpose of the P47-STG-0001 RevA Monkey Bars™ Pin-to-Bar External Fixation System Surgical Technique Guide is to demonstrate the optionality and functionality of the Monkey Bars™ Pin-to-Bar External Fixation System implants and instrumentation. Although variations in placement and use of the Monkey Bars™ Pin-to-Bar External Fixation System implants can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Monkey Bars™ Pin-to-Bar External Fixation System can be employed, appropriate for the size of the device. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.