MONKEY RINGS

SURGICAL TECHNIQUE GUIDE

Circular External Fixation

Exclusively foot & ankle

Paragon 28®

PRODUCT DESCRIPTION

The Monkey Rings™ External Fixation System allows for modular flexibility in circular external fixation constructs. Half Pin and Wire placement, as well as Construct type, will depend on the injury or condition being addressed. Ring size, use of Struts or Threaded Rods, and Half Pins or Wires is all left to surgeon discretion.

Acknowledgment:
Paragon 28® would like to thank Dr. Byron Hutchinson, DPM and Dr. Mark Easley, MD for their contribution to the surgical technique guide.

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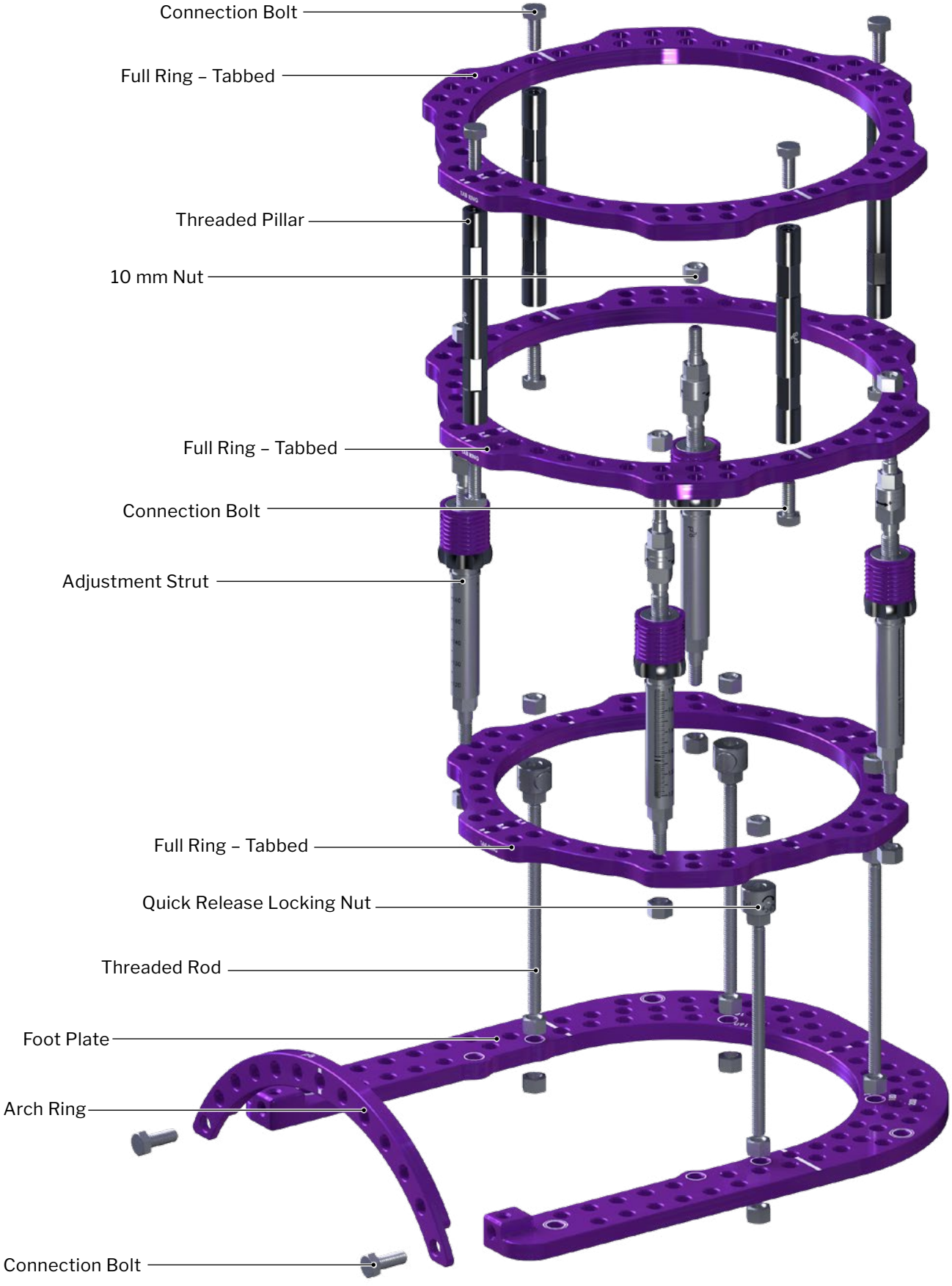
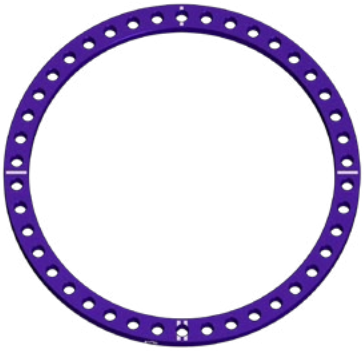
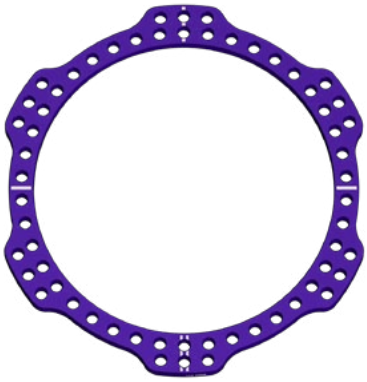
SYSTEM COMPONENTS AND INSTRUMENTATION



SYSTEM COMPONENTS AND INSTRUMENTATION

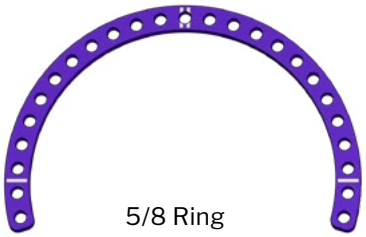


Full Ring – Single Row
(P45-111-XXXX)



Full Ring – Tabs
(P45-112-XXXX)

Tabbed 5/6 Ring
(P45-125-XXXX)

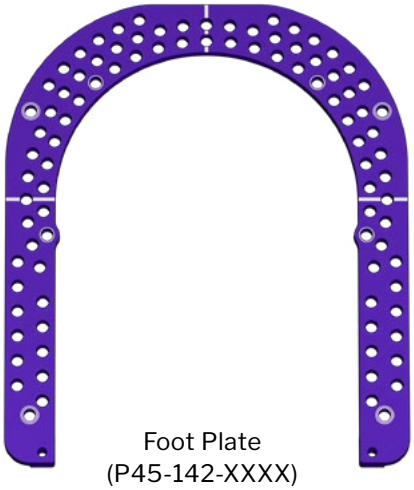


5/8 Ring
(P45-120-XXXX)

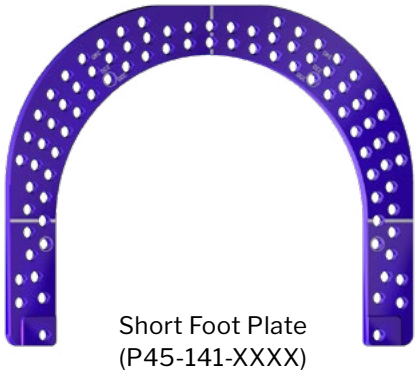
Half Ring
(P45-151-XXXX)

Arch Ring
(P45-180-XXXX)

Closure Ring
(P45-125-1XXX)



Foot Plate
(P45-142-XXXX)

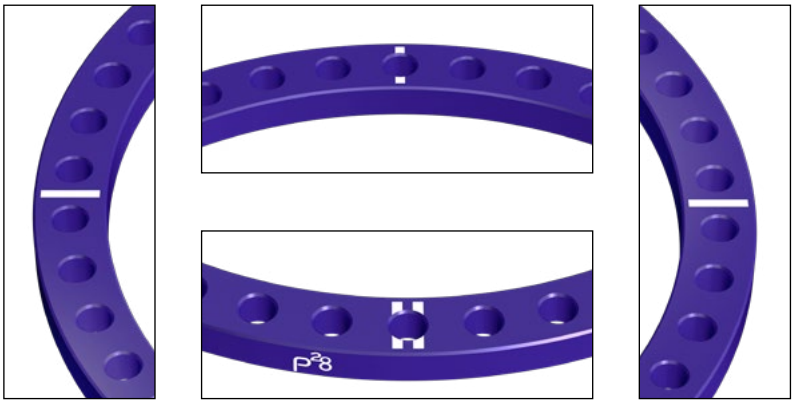


Short Foot Plate
(P45-141-XXXX)

Ring Sizers *
(P45-999-1000)

***** *Ring sizers can be ordered from marketing materials*

Posterior



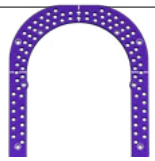
Anterior

Double marking is to denote the anterior orientation of the Ring, while the other three single markings denote the medial, lateral, and posterior orientation.

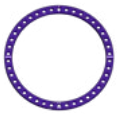
SYSTEM COMPONENTS AND INSTRUMENTATION

The size charts below depict the compatibility of the system's Ring/Foot Plates and specifies which Plates come standard in the case. All other Plate sizes are available by request.

Key:
= Available in case
= Available for order
= Sizes compatible
= Sizes non-compatible

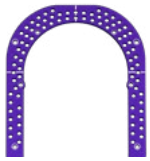


Foot Plate

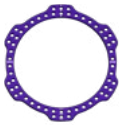


Full Ring

	120 mm	140 mm	160 mm	180 mm	200 mm	220 mm
80 mm						
100 mm						
120 mm						
140 mm						
160 mm						
180 mm						
200 mm						
220 mm						



Foot Plate



Tabbed Ring

	120 mm	140 mm	160 mm	180 mm	200 mm	220 mm
80 mm						
100 mm						
120 mm						
140 mm						
160 mm						
180 mm						
200 mm						
220 mm						

SYSTEM COMPONENTS AND INSTRUMENTATION

Key:
= Available in case
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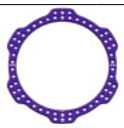
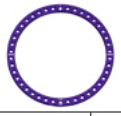
= Sizes non-compatible



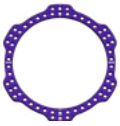
Tabbed Ring

Tabbed Ring	80 mm	100 mm	120 mm	140 mm	160 mm	180 mm	200 mm	220 mm
80 mm								
100 mm								
120 mm								
140 mm								
160 mm								
180 mm								
200 mm								
220 mm								



Full Ring

Full Ring	80 mm	100 mm	120 mm	140 mm	160 mm	180 mm	200 mm	220 mm
80 mm								
100 mm								
120 mm								
140 mm								
160 mm								
180 mm								
200 mm								
220 mm								



Tabbed Ring

Tabbed Ring	80 mm	100 mm	120 mm	140 mm	160 mm	180 mm	200 mm	220 mm
80 mm								
100 mm								
120 mm								
140 mm								
160 mm								
180 mm								
200 mm								
220 mm								

Full Ring

Full Ring	80 mm	100 mm	120 mm	140 mm	160 mm	180 mm	200 mm	220 mm
80 mm								
100 mm								
120 mm								
140 mm								
160 mm								
180 mm								
200 mm								
220 mm								

SYSTEM COMPONENTS AND INSTRUMENTATION

Bonobo™ Ball Joint Struts (P45-223-XXXX)

Strut Lengths Available			
XX-Small 47 mm - 59 mm	X-Small 57 mm - 79 mm	Small 77 mm - 118 mm	Medium 117 mm - 198 mm

Adjustment Strut (P45-224-XXXX)

Strut Lengths Available		
Small 100 mm-129 mm	Medium 120 mm-170 mm	Large 160 mm-250 mm

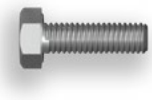
Threaded Rod (P45-310-XXXX)
Allow for the adjustments in the length between the Ring or Foot Plates.

Rod Lengths Available				
30 mm	60 mm	80 mm	100 mm	120 mm
150 mm	200 mm	250 mm	300 mm	

Threaded Pillar (P45-330-XXXX)
Threaded Pillars are available in static lengths.

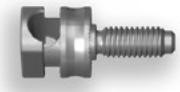
Pillar Lengths Available			
30 mm	50 mm	75 mm	100 mm
150 mm	200 mm	250 mm	300 mm

Connection Bolt
(P45-914-XXXX)



Connection Bolt Lengths Available			
8 mm	16 mm	20 mm	25 mm

Universal Pin Clamp
(P45-970-2000)



Wire Fixation Bolt
(P45-913-2001)

Russian Wire Bolt
(P45-913-2011)

Convex Spherical Washer
(P45-944-0001)

Concave Spherical Washer
(P45-944-0002)

Washer
(P45-943-XXXX)

Washer Sizes Available		
1 mm	2 mm	4 mm

SYSTEM COMPONENTS AND INSTRUMENTATION

Quick Release Locking Nut (P45-941-1002)

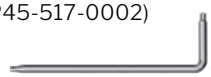
Close Encounter Nut (P45-941-0010)

M6 Bevel Nut, 10 mm Hex (P45-940-1001)

Nylon Lock Nut, 10 mm Hex (P45-940-2001)

M6 Long Extension Nut, Compression/Distraction, 10 mm Hex (P45-941-0001)

Quick Release Locking Nut Wrench (P45-517-0002)



Hinge (P45-912-1000)

Bonobo™ Modular Ball Joint (P45-233-1000)

Universal Joint (P45-912-3000)

Female Post, 1 Hole (P45-920-0001)

Ball Joint Strut Wrench (P45-517-0010)

Female Extension Posts without threaded attachment (Female) (P45-920-XXXX)

Male Extension Posts with Threaded Attachment (Male) (P45-921-XXXX)

Female Extension Post Holes Available			
1 Hole	2 Hole	3 Hole	4 Hole

Male Extension Post Holes Available		
2 Hole	3 Hole	4 Hole

Rancho Cube Post, 1 Hole (P45-926-0001)

Rancho Cubes (P45-925-XXXX)

Rancho Cube Holes Available			
2 Hole	3 Hole	4 Hole	5 Hole

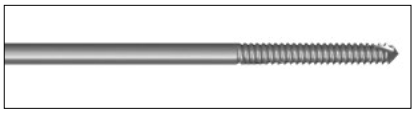
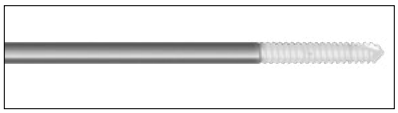
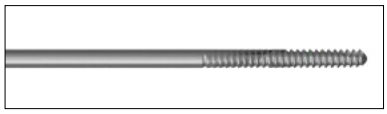
Rancho Cube Centering Collars (P45-925-XXXX)

Centering Collar Diameters Available		
4.0 mm	5.0 mm	6.0 mm

Offset Slotted Ring Adapter (Short) (P45-935-XXXX)

Offset Slotted Ring Adapter (Long) (P45-935-XXXX)

SYSTEM COMPONENTS AND INSTRUMENTATION

	Drill Tip	Diameters Available	Overall Length	Thread Length	Drill	Drill/Guide Band Color
Half Pin Size	Self-Drilling (P45-191-XXXX) 	Ø4.0	95 mm	35 mm	Ø2.4	Light Blue
		Ø5.0	95 mm	35 mm	Ø3.4	Chrome
		Ø5.0	160 mm	45 mm	Ø3.4	Chrome
		Ø6.0	160 mm	35 mm	Ø4.4	Black
		Ø6.0	160 mm	45 mm	Ø4.4	Black
	Self-Drilling (Hydroxyapatite Coating) (P45-199-XXXX-S) 					
		Ø4.0	120 mm	34 mm	Ø3.2	--
		Ø5.0	130 mm	30 mm	Ø3.2	--
		Ø5.0	130 mm	35 mm	Ø3.2	--
		Ø5.0	180 mm	50 mm	Ø3.2	--
		Ø6.0	130 mm	30 mm	Ø3.2	--
		Ø6.0	130 mm	35 mm	Ø3.2	--
		Ø6.0	180 mm	50 mm	Ø3.2	--
	Blunt Tipped (P45-196-XXXX) 					
		Ø4.0	95 mm	35 mm	Ø2.4	Light Blue
		Ø5.0	160 mm	35 mm	Ø3.4	Chrome
		Ø5.0	160 mm	45 mm	Ø3.4	Chrome
		Ø6.0	160 mm	35 mm	Ø4.4	Black
		Ø6.0	160 mm	45 mm	Ø4.4	Black
Drill Tube Size	Drill Tubes (P45-962-XXXX) 					
		Ø4.0	--	--	Ø2.4	Light Blue
		Ø5.0	--	--	Ø3.2/ Ø3.4	Chrome
		Ø6.0	--	--	Ø4.4	Black

NOTE: *Pre-drilling is always recommended regardless of Half Pin type. All HA pins, regardless of diameter, use the sterile packed 3.2mm drill, P45-960-3219-S.*

SYSTEM COMPONENTS AND INSTRUMENTATION

Smooth Wire (P45-194-XXXX)

Material	Available Wire Dimensions
Stainless Steel	*Ø1.8 x 400 mm* *Ø1.8 x 500 mm* *Ø2.0 x 400 mm* *Ø2.0 x 500 mm*
Titanium	*Ø2.0 x 400 mm*

Reduction Wire (P45-195-XXXX)

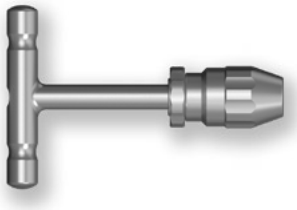
Material	Available Wire Dimensions
Stainless Steel	*Ø1.8 x 400 mm* *Ø1.8 x 500 mm* *Ø2.0 x 400 mm* *Ø2.0 x 500 mm*
Titanium	*Ø2.0 x 400 mm*

Steinman Pin (P45-192-XXXX)

Available Pin Dimensions
Ø2.3 x 230 mm *Ø3.2 x 230 mm* *Ø4.0 x 230 mm (AO Quick Connect)*

T-Handle Driver
(P47-940-0001)

Fits AO and 10 mm hex components

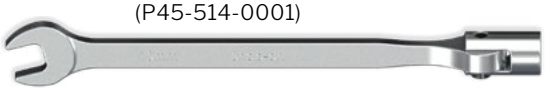


Universal T Chuck
(P45-550-0001)

10 mm Wrench
(P47-950-0001)

Ratcheting Wrench
(P45-513-0010)

Articulating Hinged Wrench
(P45-514-0001)



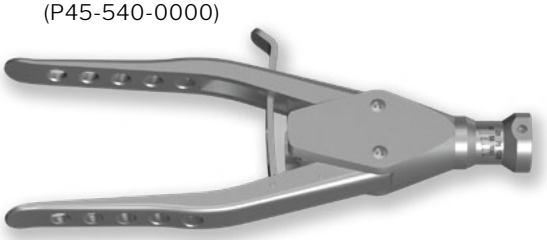
10 mm Angled Socket Wrench
(P45-513-0001)

10 mm Slotted Angled Socket Wrench
(P45-513-0002)

10 mm Tang Angled Socket Wrench
(P45-513-0003)

SYSTEM COMPONENTS AND INSTRUMENTATION

Wire Tensioner
(P45-540-0000)

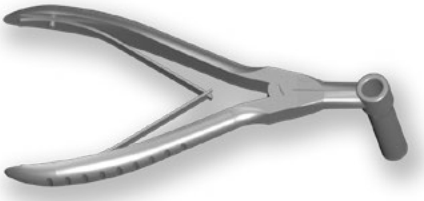


Snub Nose Attachment
(P45-540-0001)

Long Nose Attachment
(P45-540-0002)

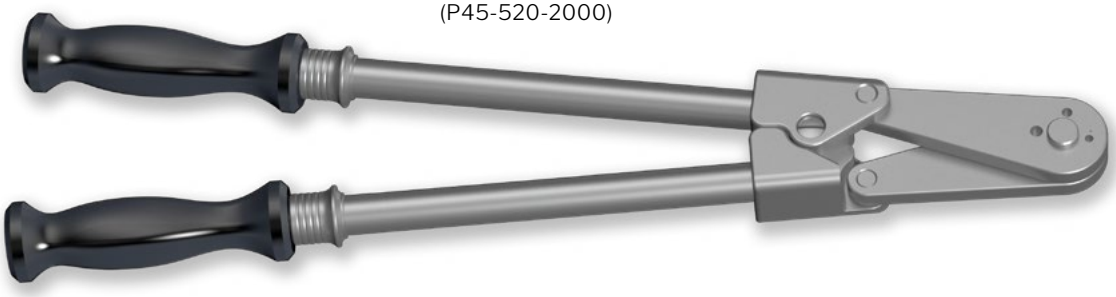
Long Range Tensioner Tip
(P45-540-0003)

Ø6.0 Split Tissue Protector Sleeve
(P45-580-1000)



Wire Cutter
(P99-150-0121)

Pin Cutter
(P45-520-2000)



Foot Rocker
(P45-170-1000)

Short Foot Rocker
(P45-170-3000)

Pin and Wire Site Protective Sponge Fasteners (*pack of 12*)
(P45-610-1000)

Infection Shielding Pin and Wire Site Protective Sponges,
Sterile Packed (pouch of 30)
(P45-600-1000-S)

Strut Locking Clip
(pouch of 10)
(P45-225-0000)

Wire Clamp Caps
(pouch of 16)
(P45-198-1000)

Protective Cap *(pouch of 10)*
(P45-198-XXXX)

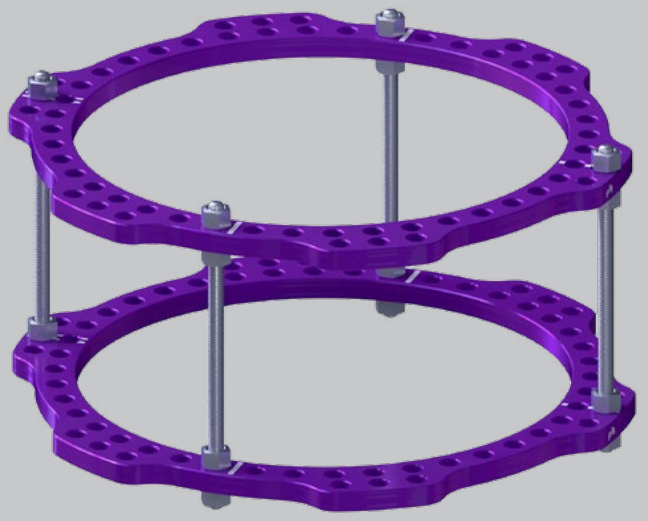
	Diameters Available		
	4.0 mm	5.0 mm	6.0 mm

FRAME BUILDING GUIDELINES

Pre-assemble the proximal tibial ring block by connecting two Full Rings. Connect using either Threaded Pillars and 16 mm Connecting Bolts or Threaded Rods and M6 Bevel Nuts affixed to both sides of each Ring, Tabbed or Single Row Full Rings may be used per surgeon preference.

NOTE: *Ring Sizers are provided to determine the correct Ring size pre-operatively. When measuring utilizing the Ring Sizer, ensure a minimum distance of 2 cm between the Ring Sizer and the skin at all points.*

OPTIONAL:



Alternatively, the proximal tibial ring block may also be built using Threaded Rods and 10 mm M6 Bevel Nuts on either side of the Full Rings.

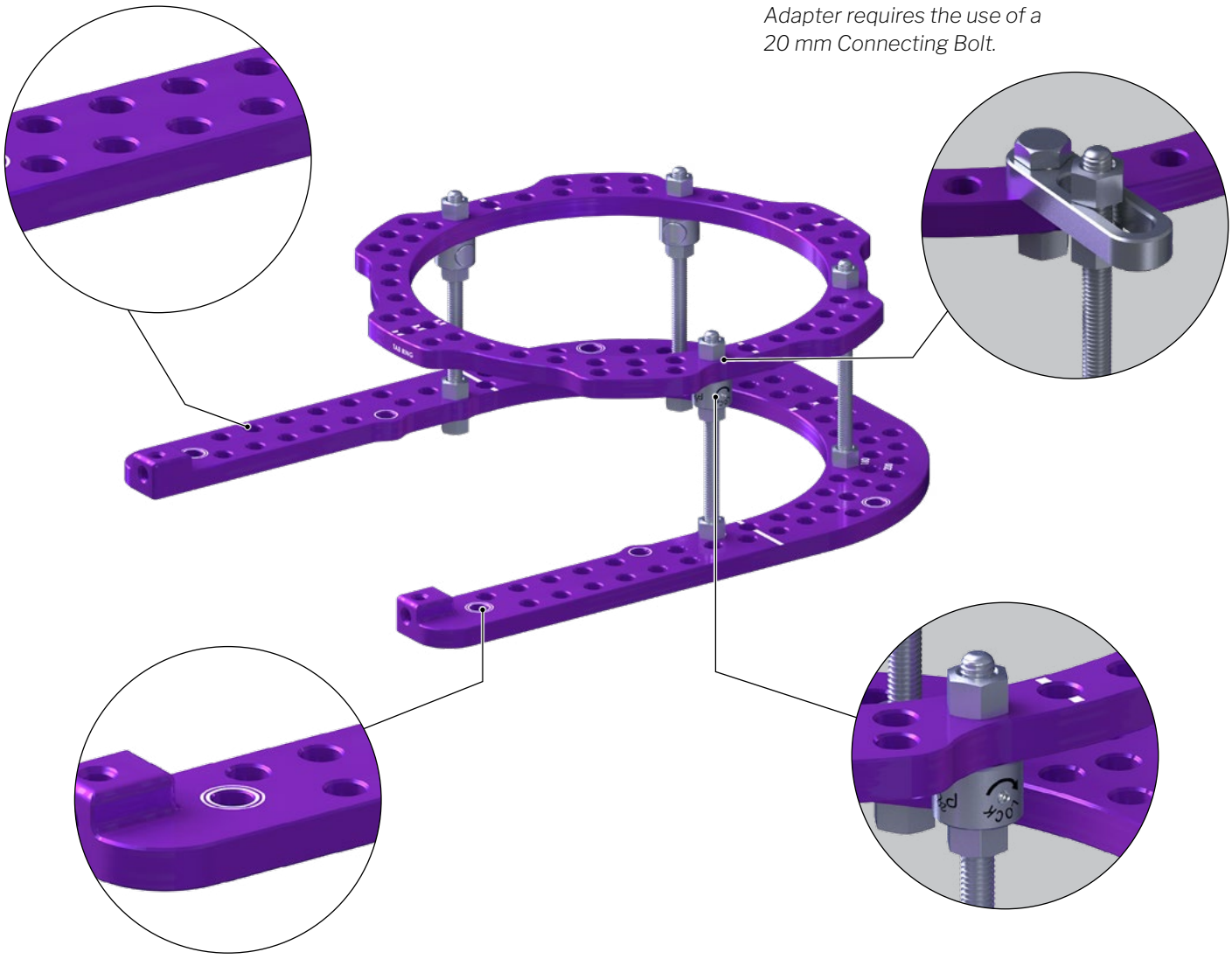
A 5/8 Ring may be used as an alternative to the most proximal Full Ring to allow for more range of motion at the knee and to prevent the posterior side of the leg from swelling into the fixator.

FRAME BUILDING GUIDELINES

Build distal Foot Plate assembly construct according to surgeon preference. Shown below is a Full Tabbed Ring attached to a Foot Plate using Threaded Rods. This can also be referred to as the distal ring block.

The Foot Plate has double rings to note the placement of the Foot Rocker at a later time.

OPTIONAL: *If the surgeon chooses to use a Single Row Full Ring, an Offset Slotted Ring Adapter is provided to taper the frame. The Offset Slotted Ring Adapter requires the use of a 20 mm Connecting Bolt.*



The two protruding holes of the Foot Plate allow for greater than 180° of functionality to increase the frame stability and are the preferred mounting site for the Threaded Rods.

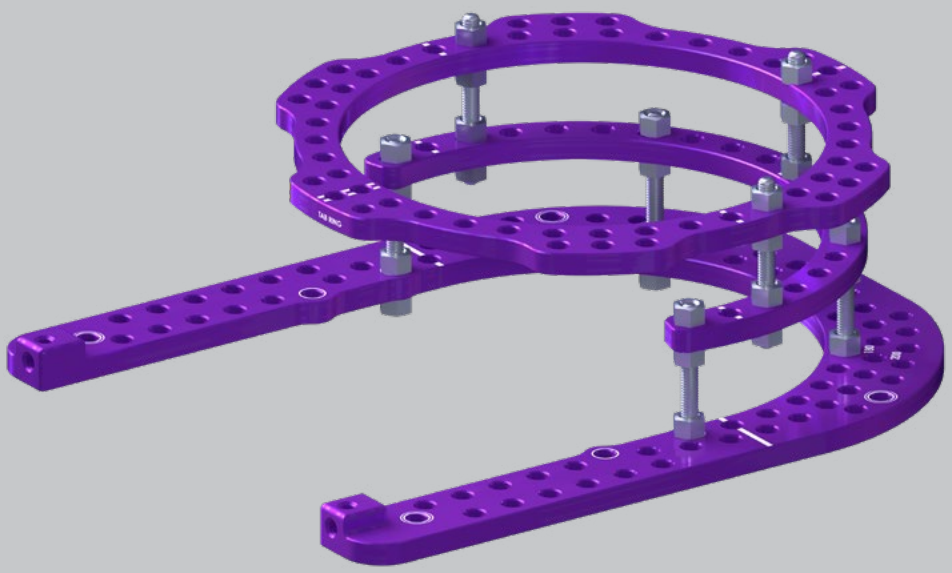
OPTIONAL: *Quick Release Locking Nuts are also provided to allow for quicker placement of each nut.*

A Quick Release Locking Nut Wrench is provided to lock the Quick Release Locking Nut in position for final tightening. It is recommended to wait until the end of the case to perform final locking of the Quick Release Locking Nut.

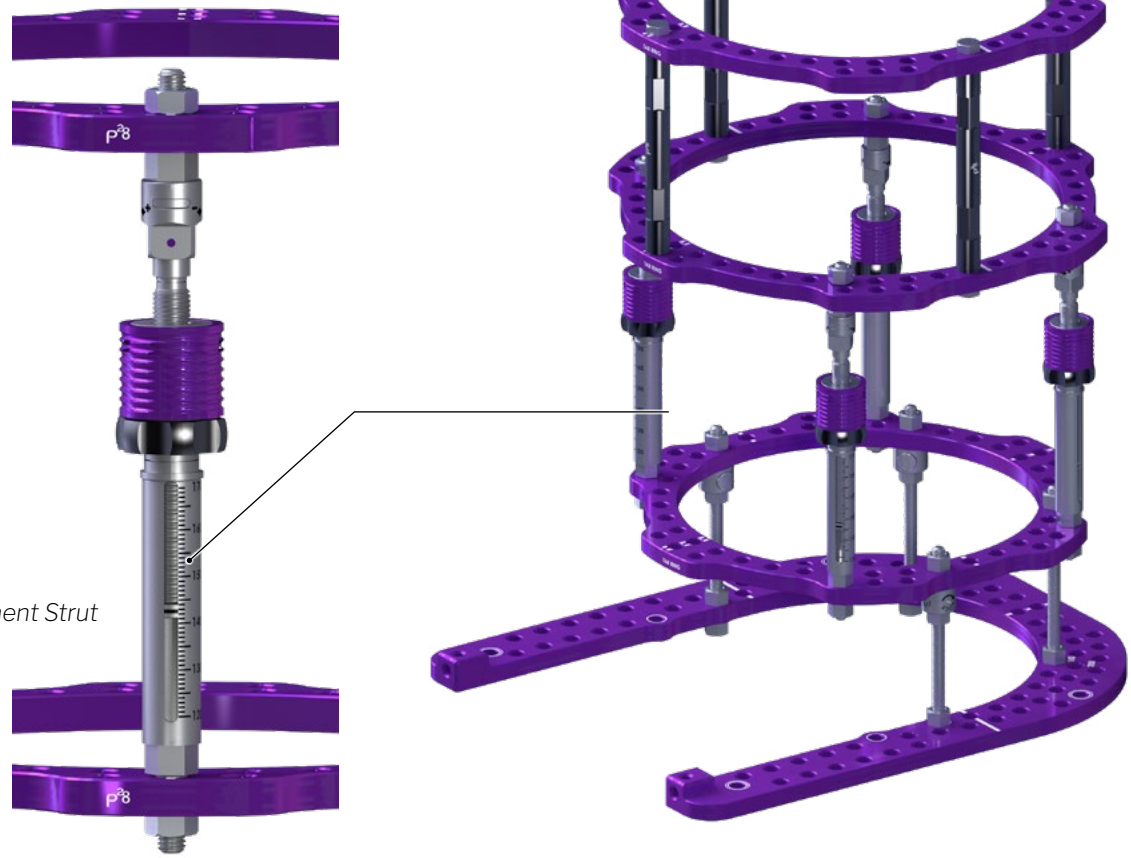
Prior to connecting the proximal and distal ring blocks, ensure the Threaded Rods are aligned with the markings on the Tabbed Full Rings. The double markings on the Rings should be oriented anterior to posterior in relation to the tibia.

FRAME BUILDING GUIDELINES

OPTIONAL:



For a constrained construct, a 5/8 Ring may also be used for placement of Wires into the talus and independent compression of the tibiotalar joint. See safe zone on page 32 for fixation placement guidelines in the talus.



Quick Adjustment Strut

Connect the distal Ring block and proximal tibial ring block using either 4 Threaded Rods or Quick Adjust Struts to allow for length adjustment of the fixator intra-operatively.

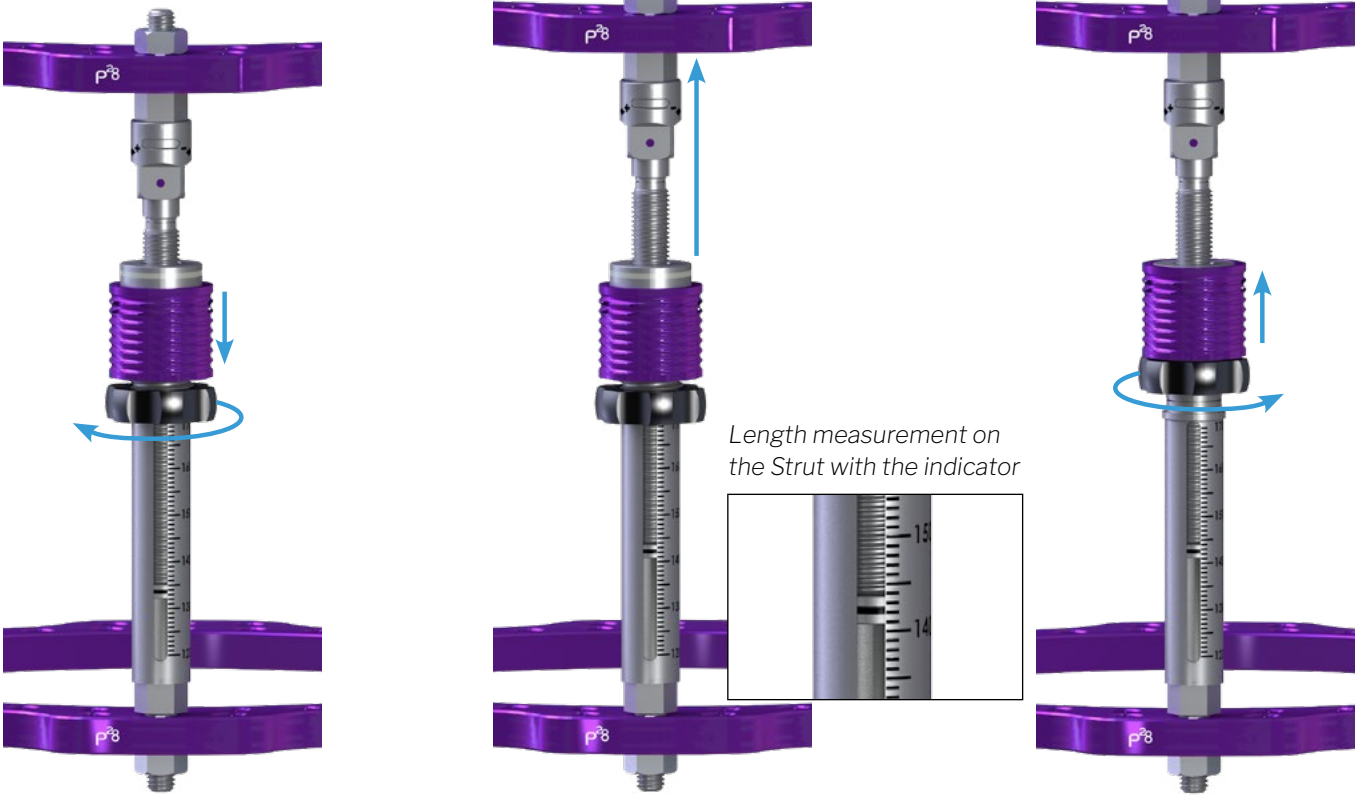
There are both a gross and fine length adjustment method to the Quick Adjust Struts.

FRAME BUILDING GUIDELINES

QUICK ADJUST STRUT FEATURES:

The Quick Adjust Struts are intended for in-line distraction (limb lengthening) or compression for fusion.

Gross Adjustment



Length measurement on the Strut with the indicator

For gross adjustments, make sure the black locking nut is disengaged by loosening completely and turning to the bottom. Pull the purple knob straight down to unlock and adjust Strut to the desired length. Confirm desired length of Strut by comparing the location of the black laser mark to the length measurements on the Strut.

Once desired length is achieved, pull the purple knob straight up and twist black locking nut clockwise to the top to lock in place. This will maintain the desired length of the Strut.

NOTE: *Confirm the purple knob is fully covering the laser marked black line and is no longer visible to ensure proper locking of the Quick Adjust Strut.*

Not fully locked (laser marking visible)

Fully locked (laser marking covered)

FRAME BUILDING GUIDELINES

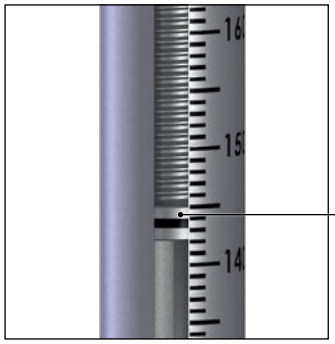
QUICK ADJUST STRUT FEATURES

Fine Adjustment

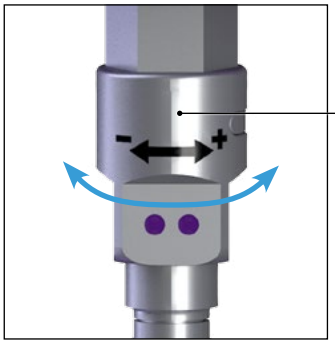
For micrometric gradual adjustment of the Strut, ensure the gross Adjustment Strut is locked in place. Use a 10mm wrench to turn the square nut containing dice in either the positive or negative direction. Each 1/4 turn of the nut results in 0.25 mm of lengthening or shortening, depending on the direction it was turned.

Four turns (one full rotation) of the square nut containing dice will result in 1 mm fine adjustment, either lengthening or shortening, depending on the direction it was turned.

NOTE: *Each Strut can be finely adjusted independent of other locked Struts up to 2mm.*

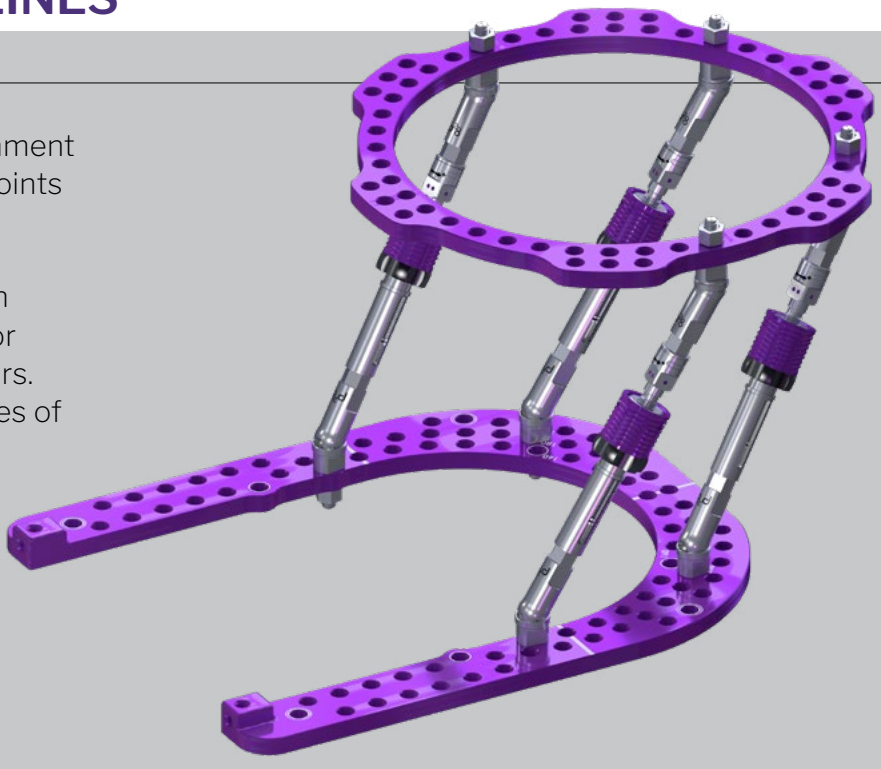


Confirm Strut length, in mm, by using the black laser mark to determine length based on where it aligns with measurements on the side.



Turn square nut portion of the Strut containing dice: toward+ sign to lengthen toward - sign to shorten.

FRAME BUILDING GUIDELINES



OPTIONAL:

For off-axis correction of deformities or alignment of boney fragments, Bonobo™ Modular Ball Joints may be used to connect Struts to the Rings.

Bonobo™ Modular ball joints can be used with the Quick Adjust Struts, threaded rods, and/or threaded rods placed through Threaded Pillars. The Modular Ball Joints allow up to 34 degrees of off-axis placement. Each ball joint used adds 37 mm length to overall Strut construct.

To use with a Quick Adjust Strut, fully thread the Modular Ball Joint to the ends of the Strut until the Ball Joint is fully seated.

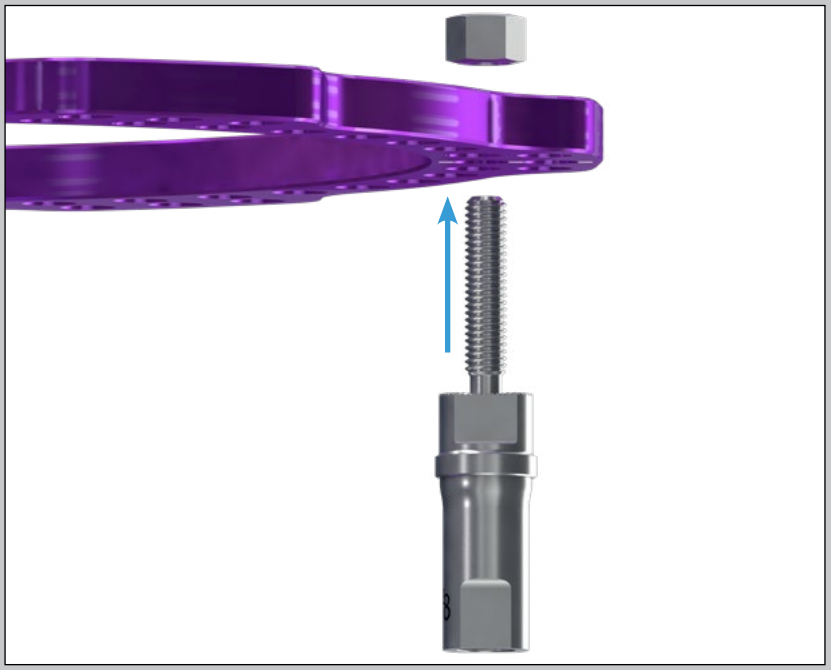
To use with a Threaded Rod, first thread on an M6 Connecting Nut. Tighten the Nut to the back of Modular Ball Joint after it has been fully threaded onto the Threaded Rod.

To use with a Threaded Pillar, place a Threaded Rod through the pillar and place ball joint on Threaded Rod as previously described.

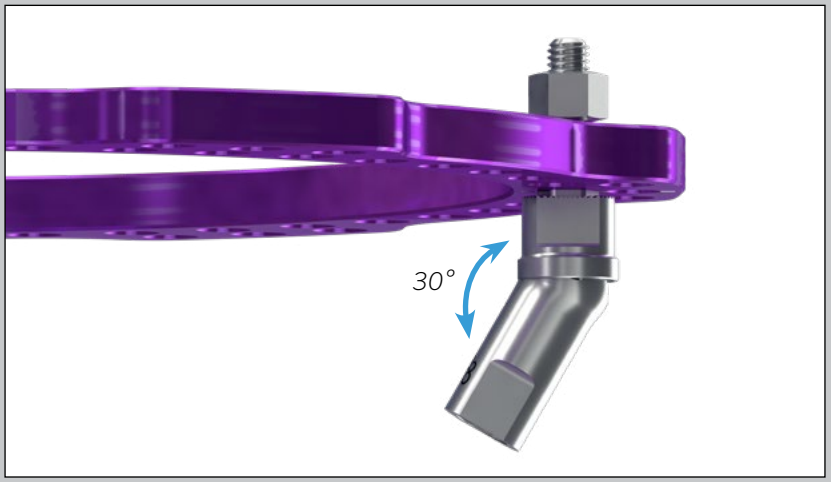
FRAME BUILDING GUIDELINES

OPTIONAL:

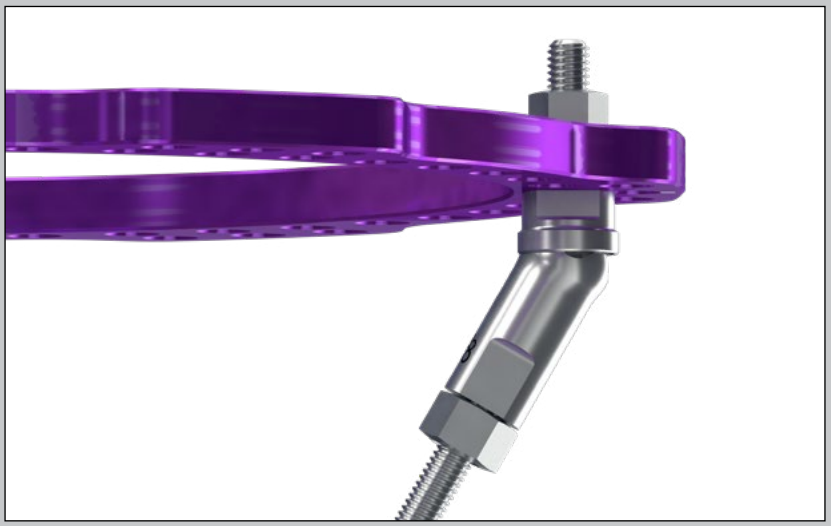
To use the joint with the Rings, place the post portion of the Modular Ball Joint through the ring and connect to the ring with a M6 Connecting Nut.



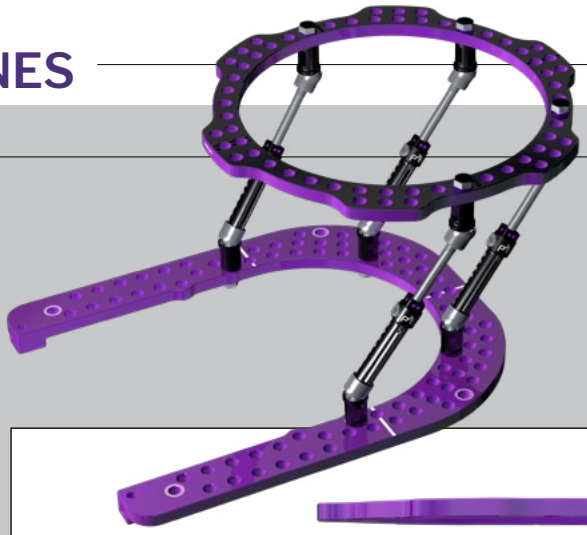
Adjust the ring to the desired position and finger tighten the bolts to hold the position of the ring.



Once desired position is achieved, fully tighten all the nuts with one of the provided wrenches and confirm correct orientation of the ring.



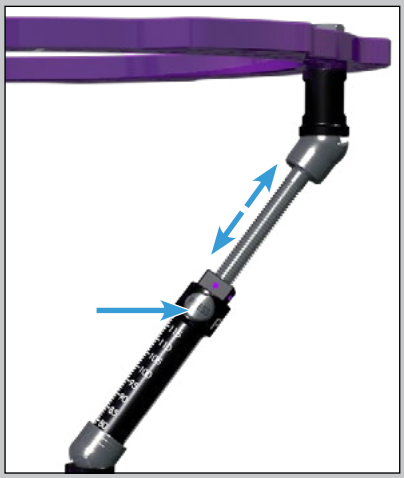
FRAME BUILDING GUIDELINES



OPTIONAL:

The Bonobo™ Ball Joint Struts can be used for acute correction and stabilization, while allowing for post-operative compression. They should not be used for gradual deformity correction. They allow for greater flexibility and reduction capabilities, but are not intended for large scale axial adjustment.

Connect the Struts to the Ring with 16 mm connection bolts, do not fully secure to the ring until the desired orientation is achieved. The Struts allow for up 34° off-axis placement in one direction and up to 68° conical off axis placement.



For gross adjustments, make sure the black press button is proud. The threaded rod can freely slide up and down for gross adjustment. Confirm desired length of the Struts by comparing the location of the black laser mark to the length measurement on the Strut.

Once desired length is achieved, press in the button. This will maintain the desired length of the Strut and it is now in fine adjustment.

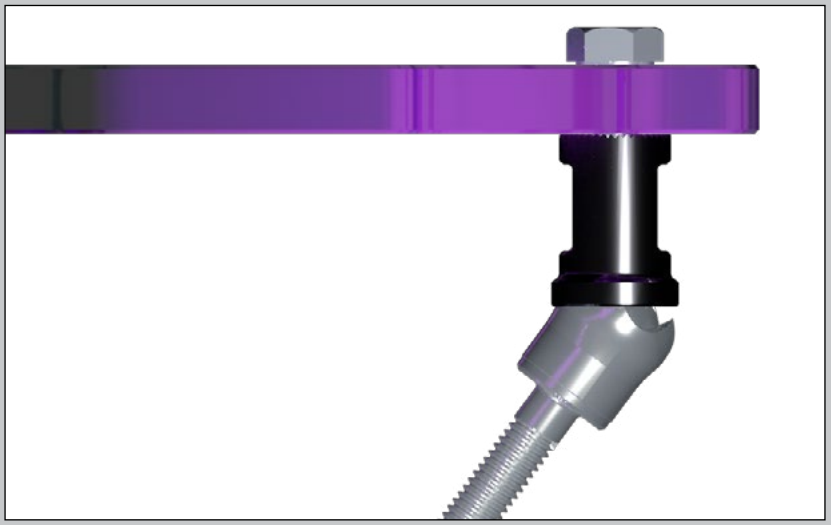
FRAME BUILDING GUIDELINES

OPTIONAL:

For fine adjustment of the Strut, the black tube can be turned counterclockwise (increasing in purple dots) to lengthen the Strut/extend the assembly.

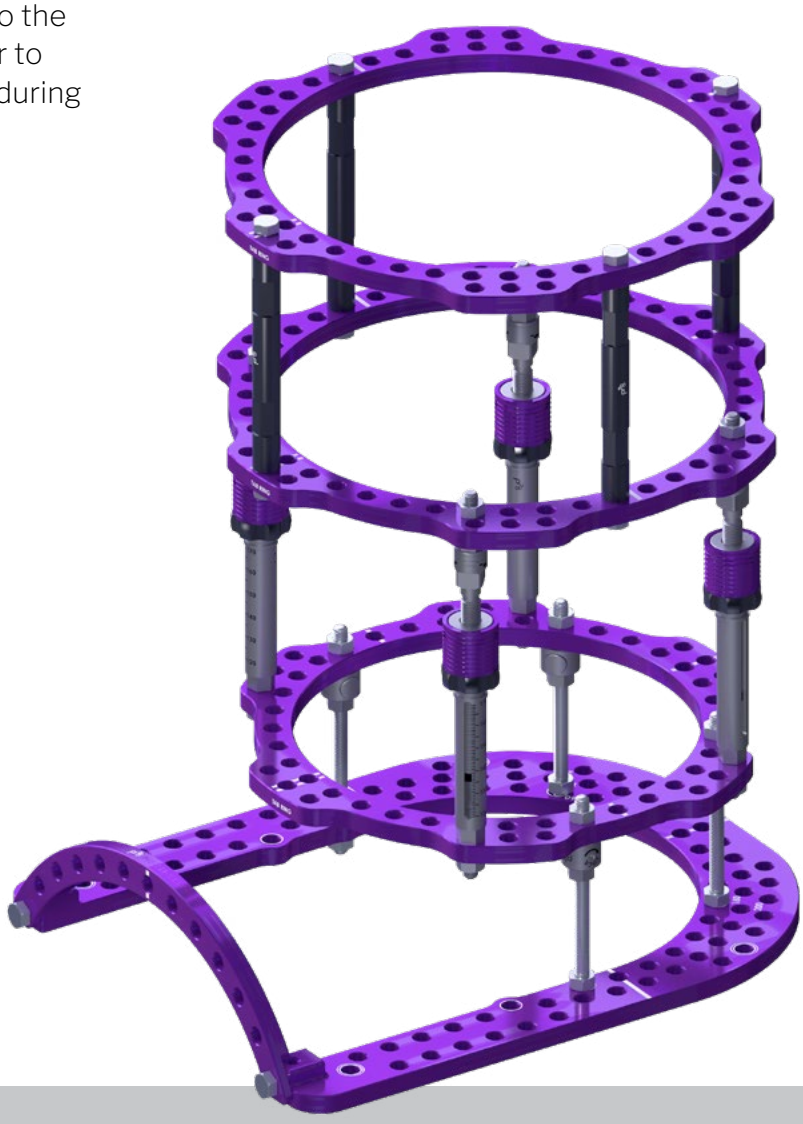
To lock the Strut in fine adjustment, the set screw can be tightened into the button with the quick release locking nut wrench or ball joint strut wrench.

Confirm proper orientation of the rings and length of the struts and fully tighten all bolts with a provided wrench.



FRAME BUILDING GUIDELINES

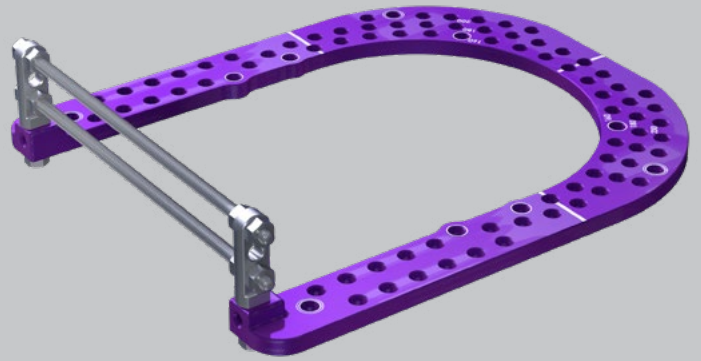
An Arch Ring is recommended to be connected to the Foot Plate using 16 mm Connecting Bolts in order to prevent deformation of the Foot Plate construct during Wire tensioning.



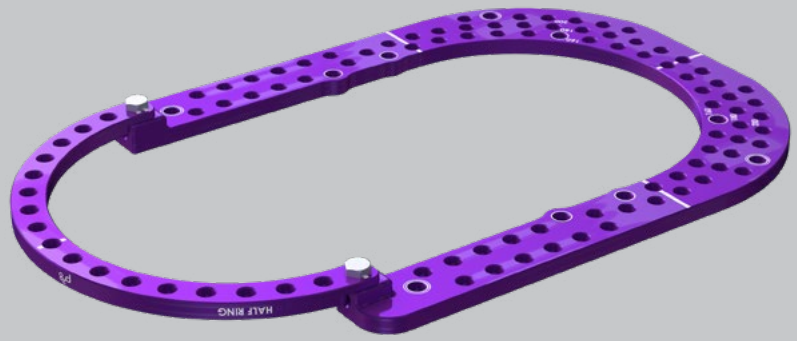
NOTE: *When connecting components to the anterior holes of the short foot plate, use the 20 mm Connecting Bolts.*

OPTIONAL:

Threaded Rod with Extension Post



Horizontal Half Ring



Alternative constructs for Foot Plate closure may be used, including Extension Posts with Threaded Rods or a horizontal Half/Arch Ring for support.

CIRCULAR EXTERNAL FIXATION APPLICATION

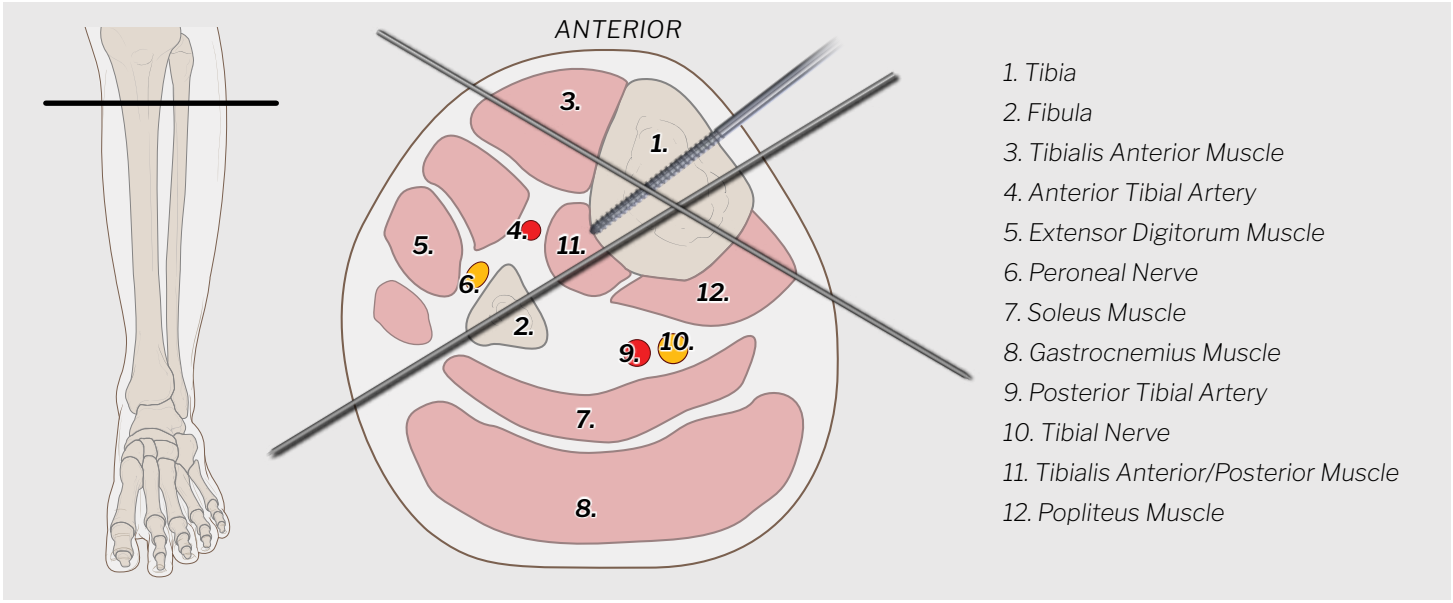
Position the patient's ankle joint at a 90° neutral position and align the Foot Plate with the plantar aspect of the foot. Ensure there is a minimum 2 cm distance from the fixator and any soft tissue on the patient.

CIRCULAR EXTERNAL FIXATION APPLICATION

After sizing the frame on the patient, move the frame slightly proximal, away from the calcaneus, place a 1.8 mm Smooth Wire through the calcaneus from medial to lateral in the posterior calcaneal tuberosity. Slide the Foot Plate down to the reference Wire and connect the Smooth Wire to the Foot Plate using a Wire Fixation Bolt and M6 Bevel Nuts. Tighten, but do not tension the Smooth Wire and confirm position of the foot is correct.

NOTE: *For Charcot foot deformity, place the foot minimally below Foot Plate with Foot Rockers to load the frame. For limb lengthening, place foot further below Foot Plate so the patient is loading the bone and not the frame.*

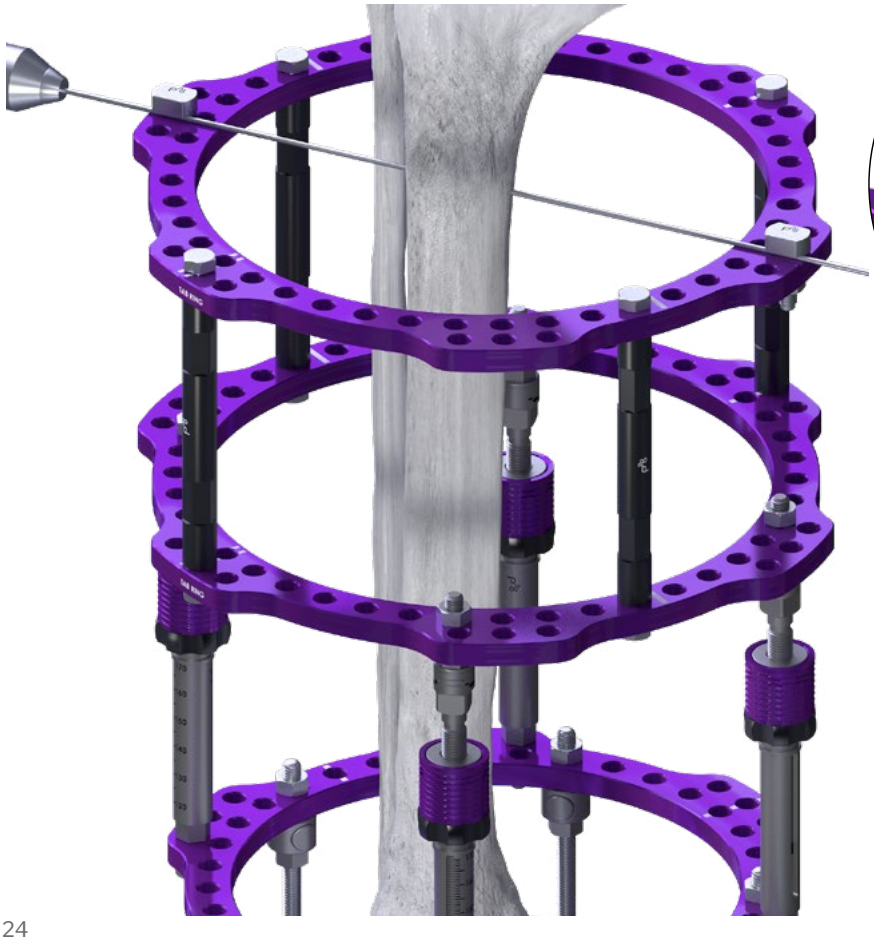
CIRCULAR EXTERNAL FIXATION APPLICATION

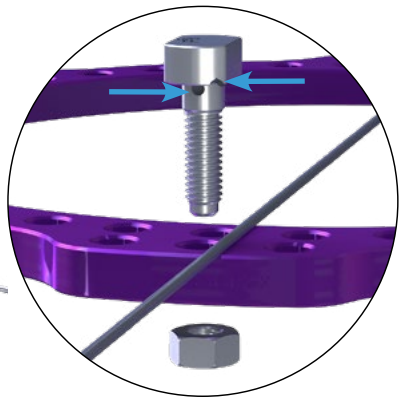


1. Tibia
2. Fibula
3. Tibialis Anterior Muscle
4. Anterior Tibial Artery
5. Extensor Digitorum Muscle
6. Peroneal Nerve
7. Soleus Muscle
8. Gastrocnemius Muscle
9. Posterior Tibial Artery
10. Tibial Nerve
11. Tibialis Anterior/Posterior Muscle
12. Popliteus Muscle

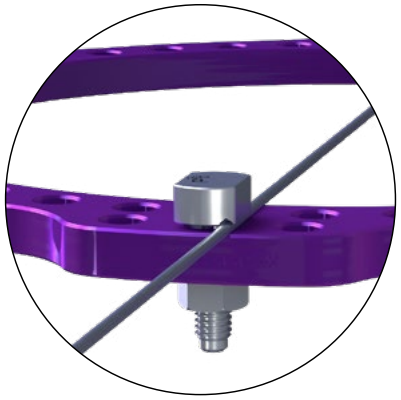
Care should be taken to avoid all major landmarks depicted above.

Position the proximal portion of the tibia either center or slightly anterior, relative to the proximal tibial ring block. Place a Smooth 1.8 mm Wire bi-cortically, lateral to medial, while keeping on same plane and level as the fixator. Ensure the frame is orthogonal to the patient and that there is at least 2 cm of clearance from the frame to the soft tissue at all points. Once the desired position is obtained, affix the Wire to the frame using Wire Fixation Bolts and 10 mm M6 Bevel Nuts. Tighten, but do not tension the Wire. Smooth or Reduction Wires may be used per surgeon preference.





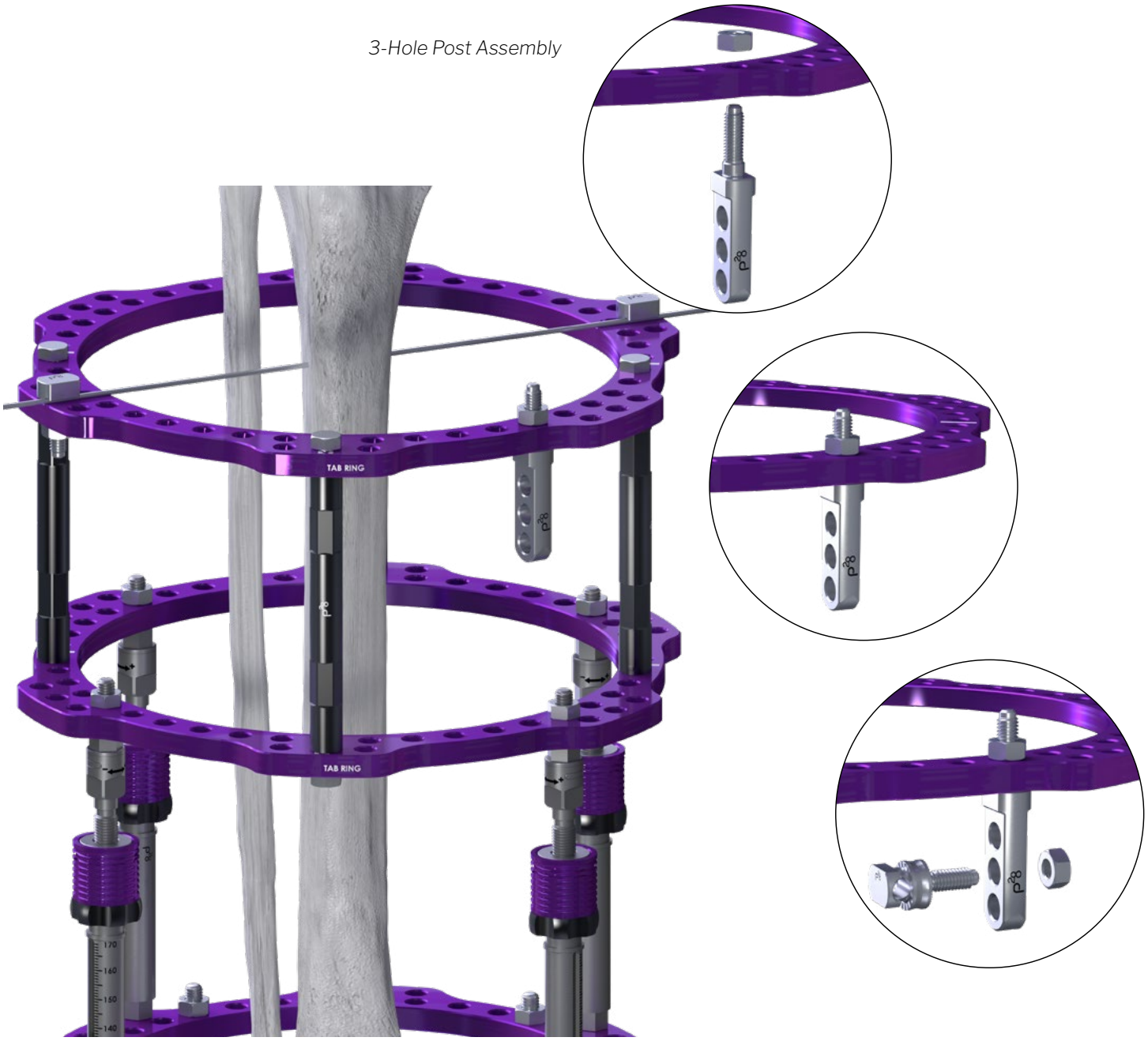
The Wire may be placed either through the center hole or the offset hole of the Wire Fixation Bolt.



CIRCULAR EXTERNAL FIXATION APPLICATION

Attach either a 3, 4, or 5-Hole Post or Rancho Cube to the most proximal Full Ring, to attach either a 4, 5, or 6 mm Half Pin. Drilling is required to place a Blunt Half Pin and recommended for placement of a Self-Drilling Half Pin for optimal performance and bone purchase.

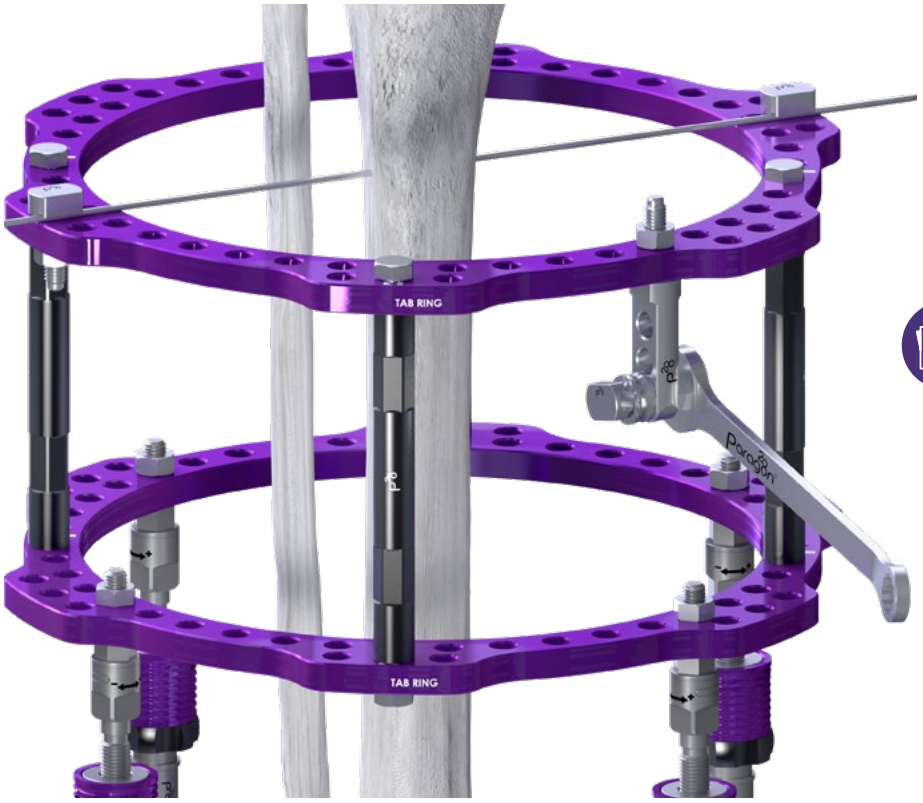
3-Hole Post Assembly



Half Pin Diameter	Drill Diameter
Ø4.0 mm	2.4 mm
Ø5.0 mm	3.4 mm
Ø6.0 mm	4.4 mm

CIRCULAR EXTERNAL FIXATION APPLICATION

Secure the Pin Clamp to the Post using the a 10 mm Nut using the provided 10 mm Wrench.



NOTE: *If Wire is placed on a Post, do not tension past 75 kg. If Wire is positioned on an open 5/8 Ring, do not tension past 90 kg.*

Location	Tension (kg)
Tibia	125 kg
Midfoot/Calcaneus	90-100 kg
Forefoot	50-70 kg

An optional Ø6.0 Split Tissue Protector Sleeve is provided for all Half Pins.

Thread the appropriate drill tube through the Pin Clamp for the appropriate sized Half Pin Drill. Read the depth markings on the drill to determine the appropriate length pin to be used.

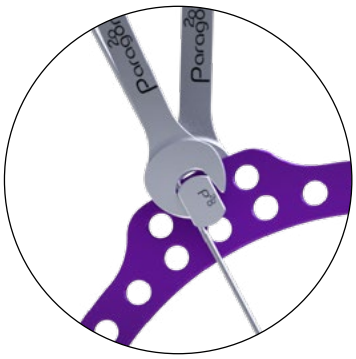
CIRCULAR EXTERNAL FIXATION APPLICATION

The Half Pin should be placed bi-cortically manually with the T-handle to avoid driving the Half Pin too far past the second cortex.

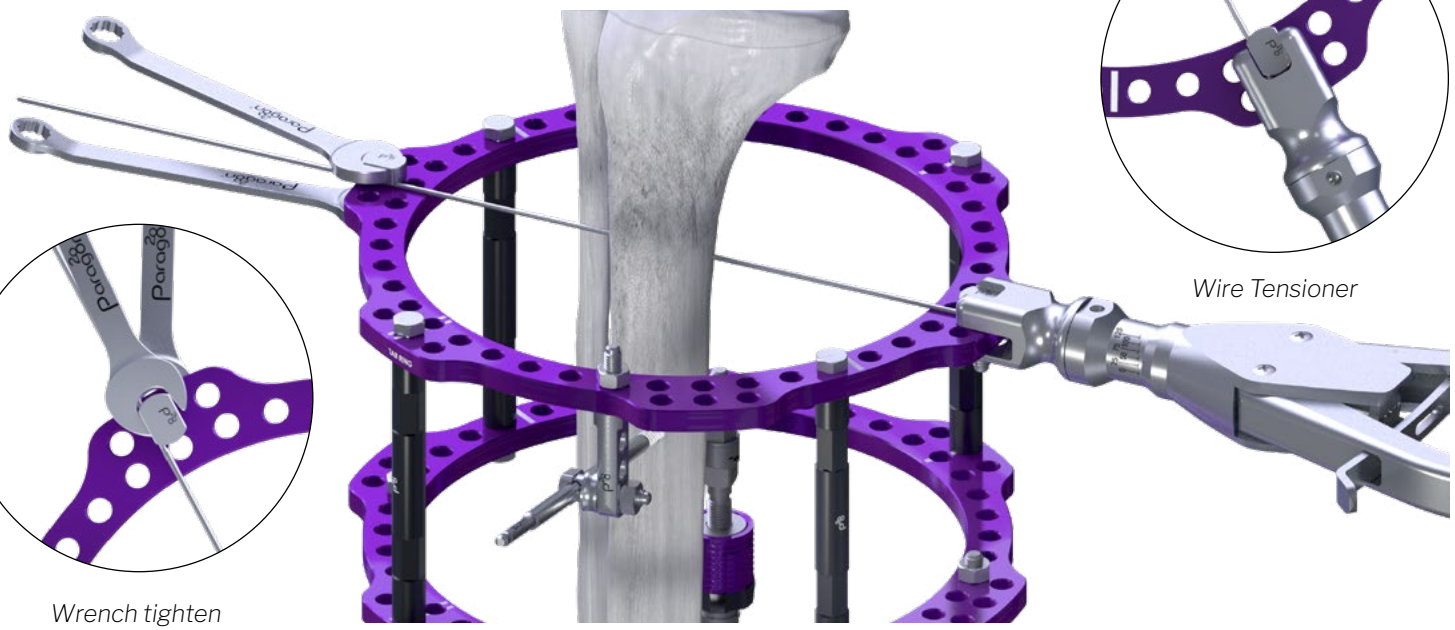
Once the Proximal Half Pin is placed, the Wire may be tensioned. Fully secure one end of the Wire and tension from the opposite end of the Wire until 125 kg of tension is reached. Wrench tighten all nuts and bolts after reaching appropriate tension.

NOTE: *Check for bicortical placement of the Half Pin under fluoroscopy prior to cutting the Half Pin. When tensioning bolt on the same side as the wire tensioner, use one of the angled socket wrenches.*

Wire Tensioner

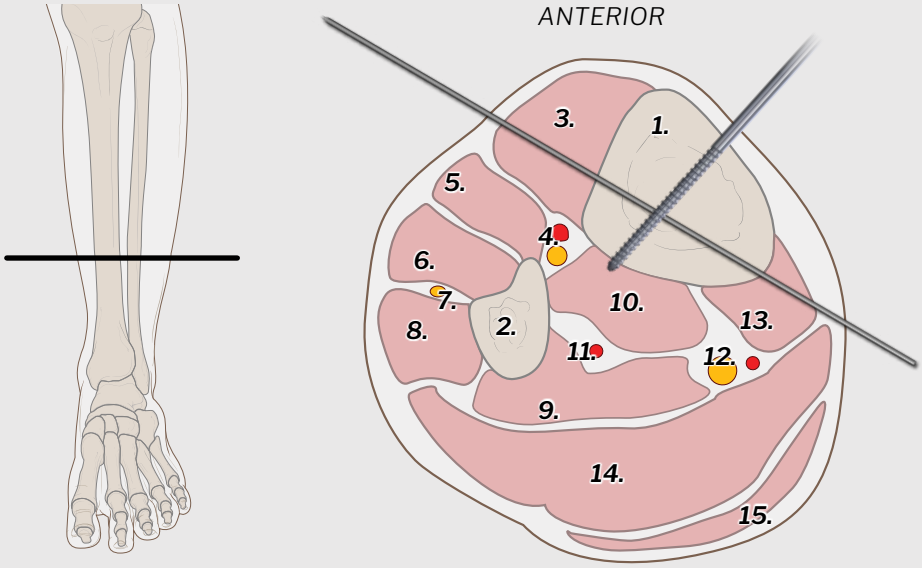


Wrench tighten



NOTE: *Both a Snub Nose and Long Nose attachment are offered per surgeon preference.*

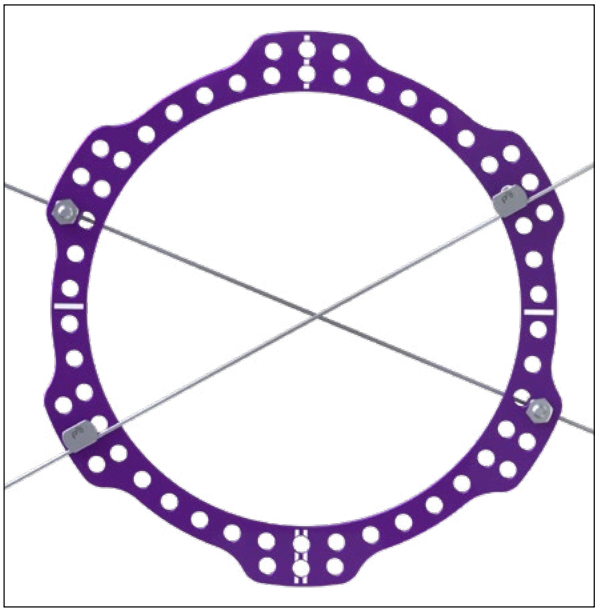
CIRCULAR EXTERNAL FIXATION APPLICATION

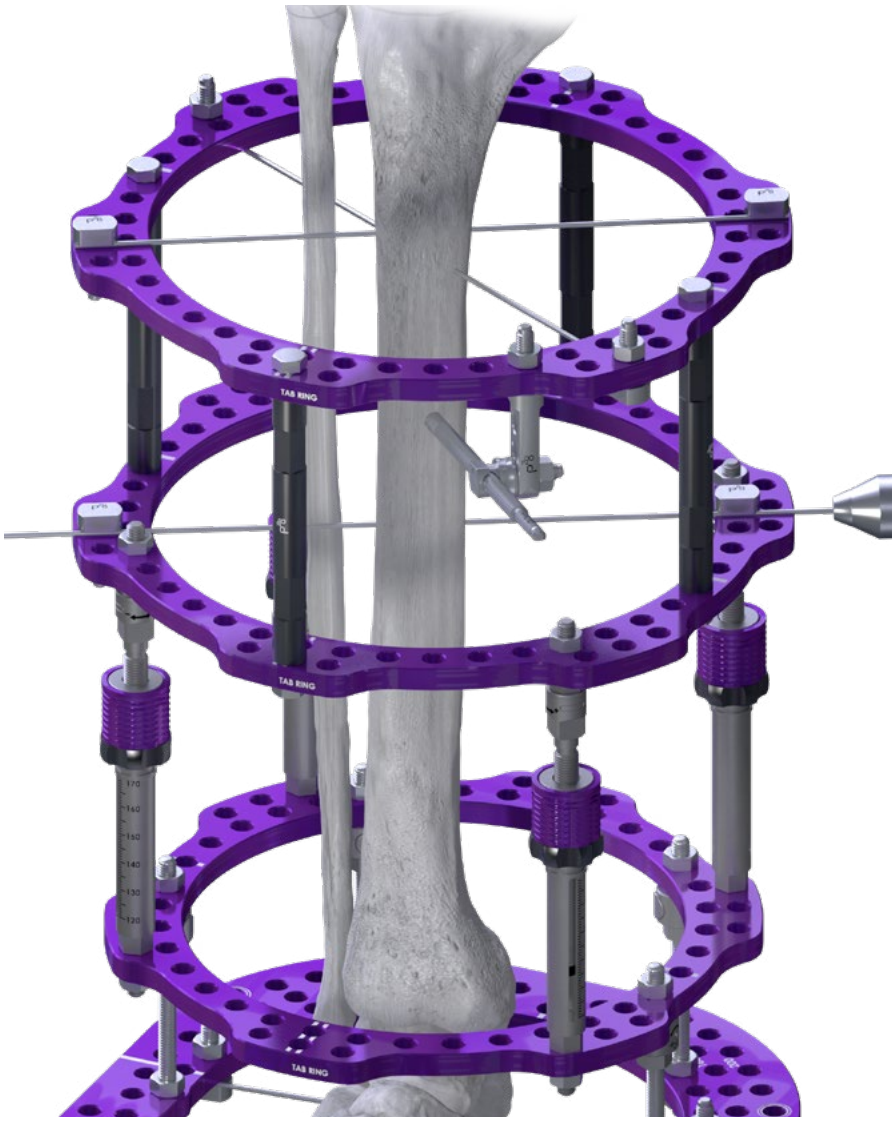


1. Tibia
2. Fibula
3. Tibialis Anterior Muscle
4. Anterior Tibial Artery
5. Extensor Digitorum Muscle
6. Peroneus Brevis Muscle
7. Peroneal Nerve
8. Peroneus Longus Muscle
9. Flexor Hallucis Longus Muscle
10. Tibialis Posterior Muscle
11. Peroneal Artery
12. Tibial Nerve
13. Flexor Digitorum Muscle
14. Soleus Muscle
15. Gastrocnemius Muscle

Care should be taken to avoid all major landmarks depicted above.

A Wire should be placed through the tibia at the second most proximal Tabbed Ring of the frame. Loosely secure the Wire using Wire Bolts during the placement of the Half Pin to allow for minor adjustments.

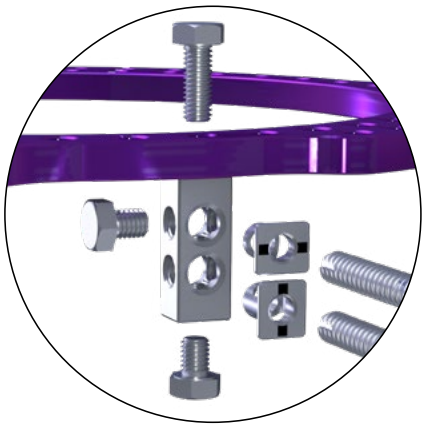




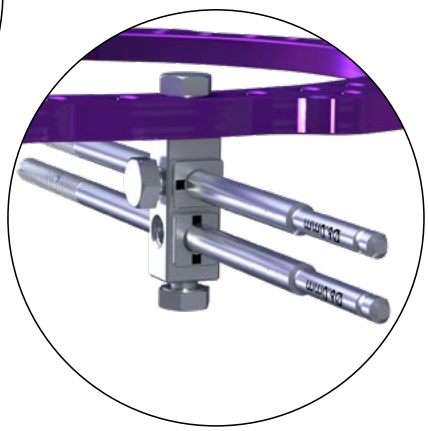
NOTE: *If two Wires are used in a single Ring, each Wire should alternate in placement to be above and below the Ring.*

CIRCULAR EXTERNAL FIXATION APPLICATION

Per surgeon preference, a second Half Pin may be placed at the second most proximal Tabbed Full Ring. Refer to page 24 for instruction on Half Pin placement.

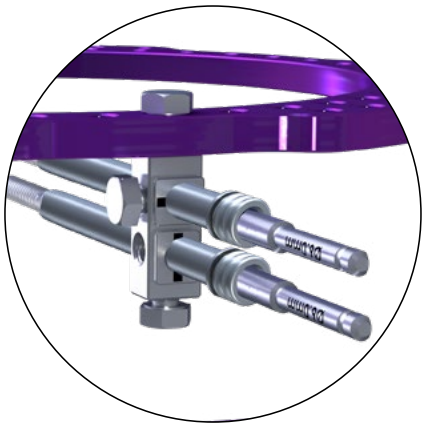


Rancho Cube assembly with Rancho Cube Centering Collars



Half Pins used in the same plane are used in this image to show the function of the Rancho Cube, but only one Half Pin per plane is recommended.

NOTE: *The laser etching of the Rancho Cube Centering Collar must be in the same orientation as the 8 mm Connecting Bolt to lock the Centering Collar in place.*



Drill tube can be placed through Rancho Cube Centering Collar

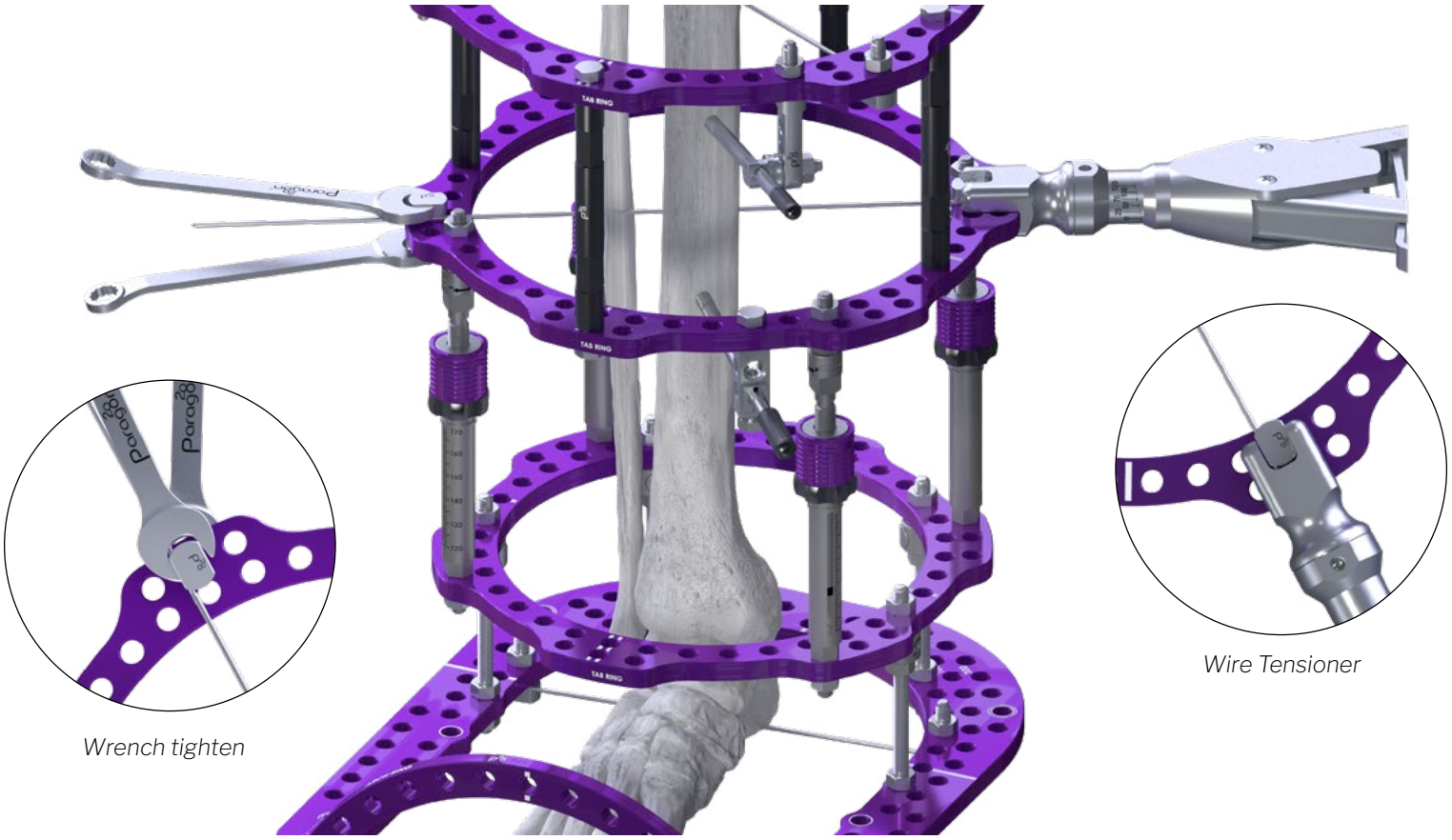
NOTE: *When using HA pins, regardless of diameter, with a Rancho Cube and Centering Collar, place the Pin through the Rancho Cube. Slide the Centering Collar over the power connection end of the Pin and align in Rancho Cube with Connection Bolt before advancing Pin into bone.*

OPTIONAL:

The Monkey Rings™ system is designed to work with the The Monkey Bars™ Pin to Bar External Fixation System Clamps. The Threaded Pillars are 11 mm, in order to accommodate a combination clamp attachment. A Monkey Bar, 11 mm Bar, and 5 mm Pin Combination Clamp may be used to attach a 5 mm Half Pin directly to the Monkey Rings Threaded Pillar.

CIRCULAR EXTERNAL FIXATION APPLICATION

Fully tighten one Wire Bolt per Wire at this time using the provided Wrench. Tension the Wire until 125 kg of tension is reached.

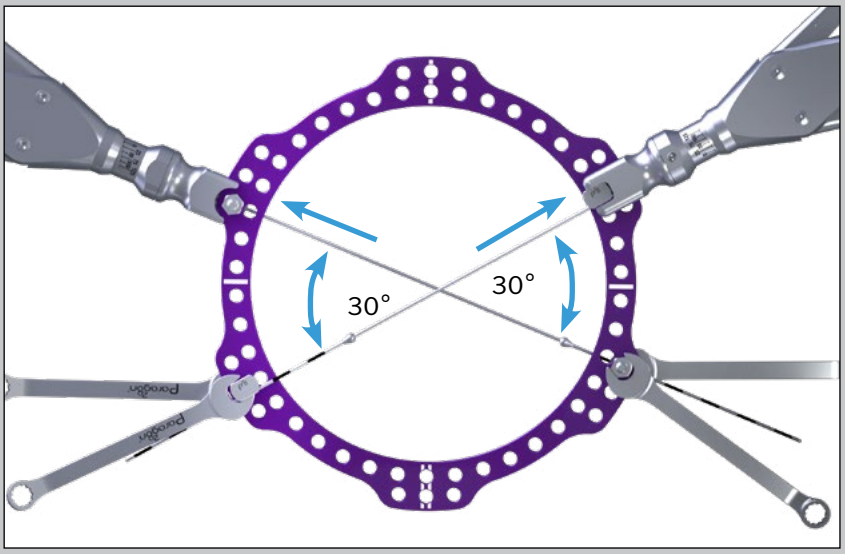


Wrench tighten

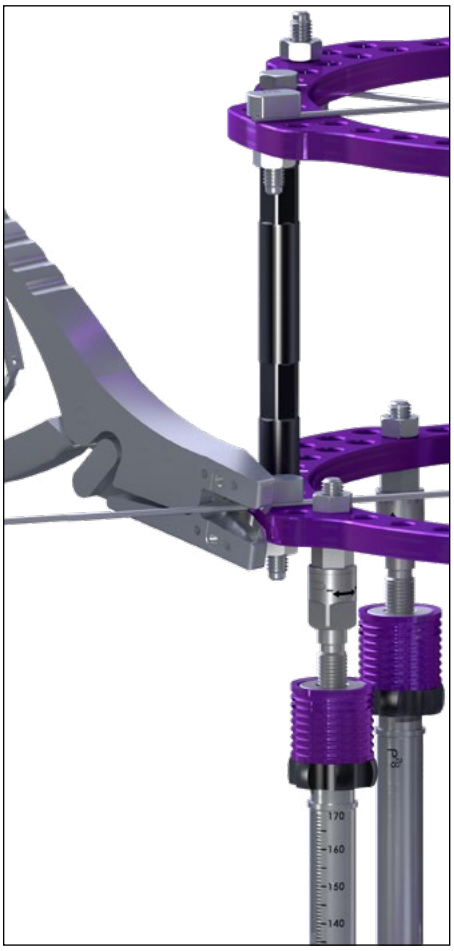
Wire Tensioner

OPTIONAL:

If two Wires are used on the same Ring, absent of any Half Pins placed, simultaneous tensioning should be performed to prevent deformation of the Ring. An angle of 30° to 60° is recommended between each Wire to prevent the bone from translating after Wire fixation is placed. Placement of opposite side Reduction Wires, as shown in this image, will also help prevent translation in the bone and increase stability. If using Reduction Wires, make sure the olive portion of the Wires is apposed to the bone prior to tensioning.



CIRCULAR EXTERNAL FIXATION APPLICATION

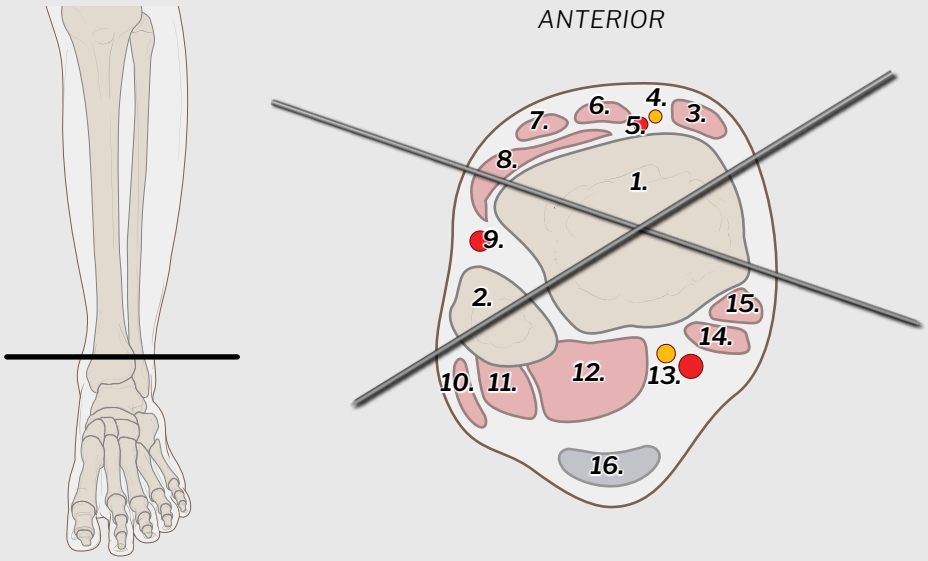


Any excess Wires may be removed using the provided Wire Cutters.

Any excess Half Pin may be removed using the provided Pin Cutters.

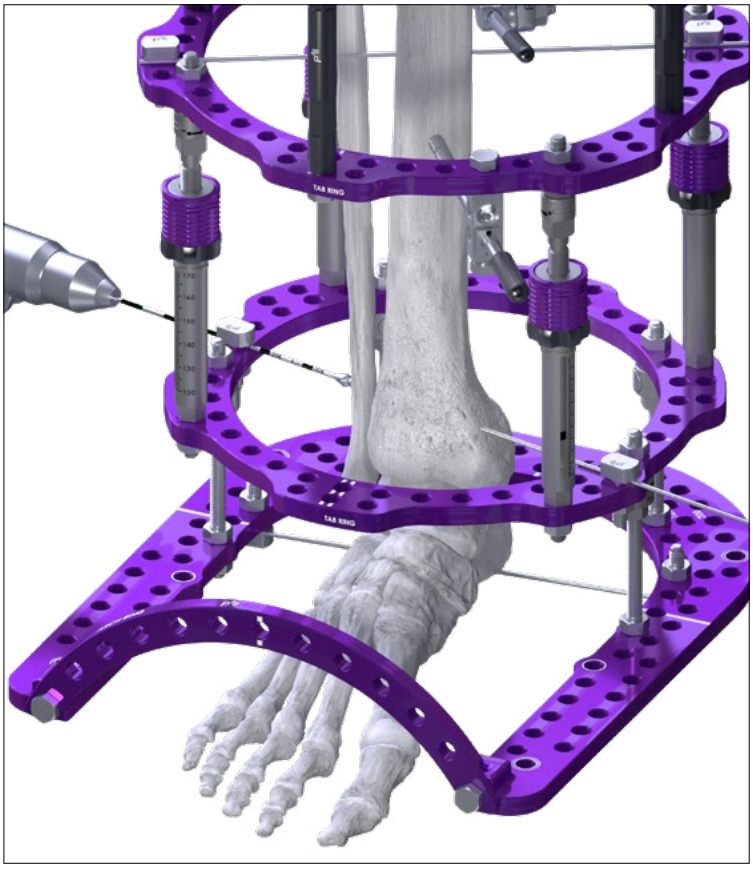
Per surgeon preference, a Pin Cap may be place over the cut end of the Half Pin.

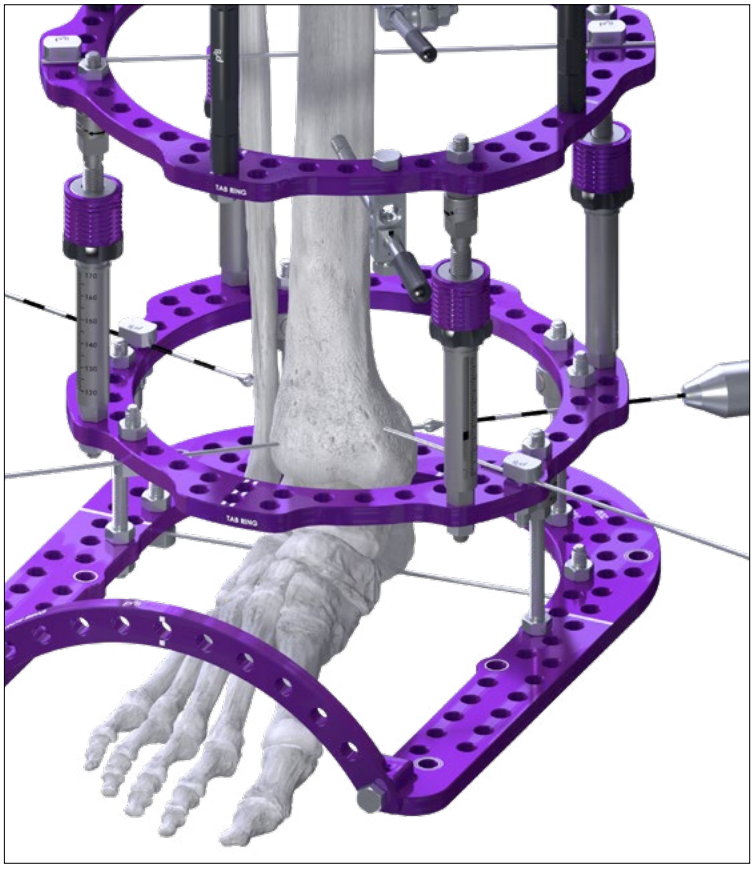
CIRCULAR EXTERNAL FIXATION APPLICATION



1. Tibia
2. Fibula
3. Tibialis Anterior Muscle
4. Peroneal Nerve
5. Anterior Tibial Artery
6. Extensor Hallucis Muscle
7. Extensor Digitorum Longus Muscle
8. Peroneus Tertius Muscle
9. Peroneal Artery
10. Peroneus Longus Muscle
11. Peroneus Brevis Muscle
12. Flexor Hallucis Longus Muscle
13. Posterior Tibial Artery and Nerve
14. Flexor Digitorum Muscle
15. Tibialis Posterior Muscle
16. Achilles Tendon

Care should be taken to avoid all major landmarks depicted above.

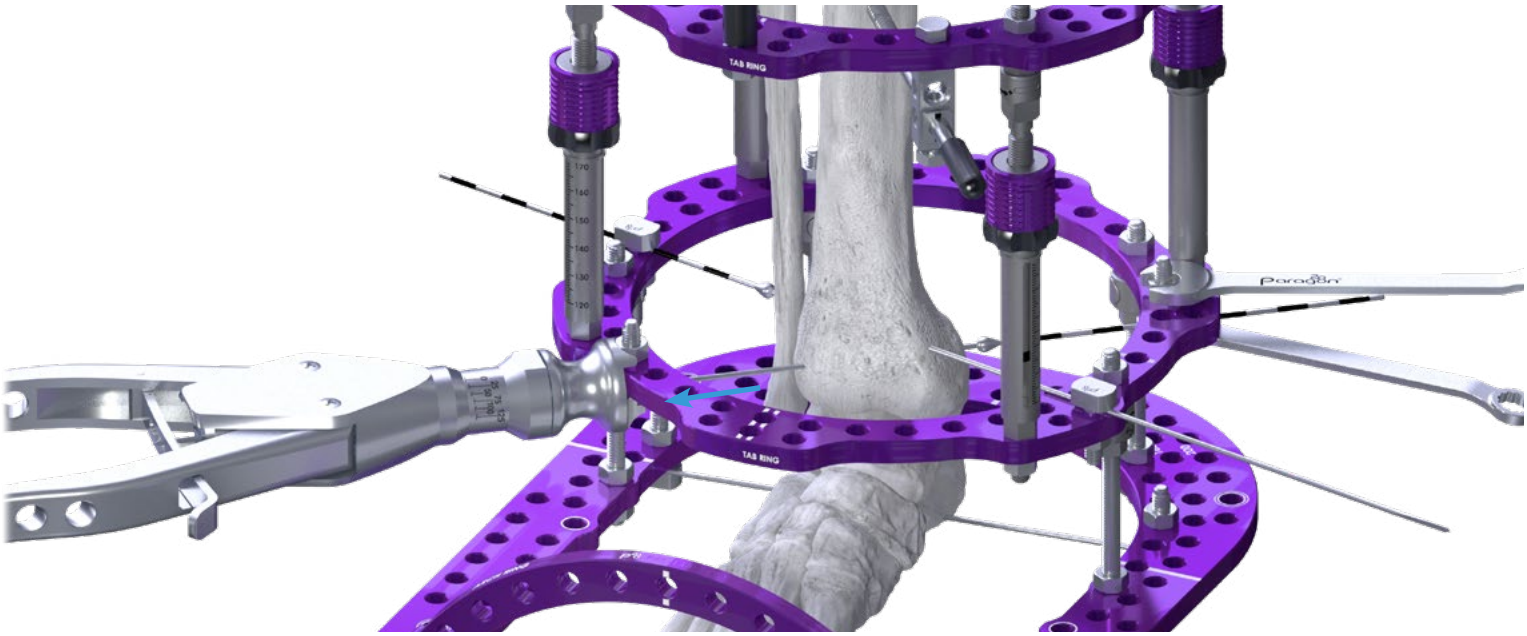




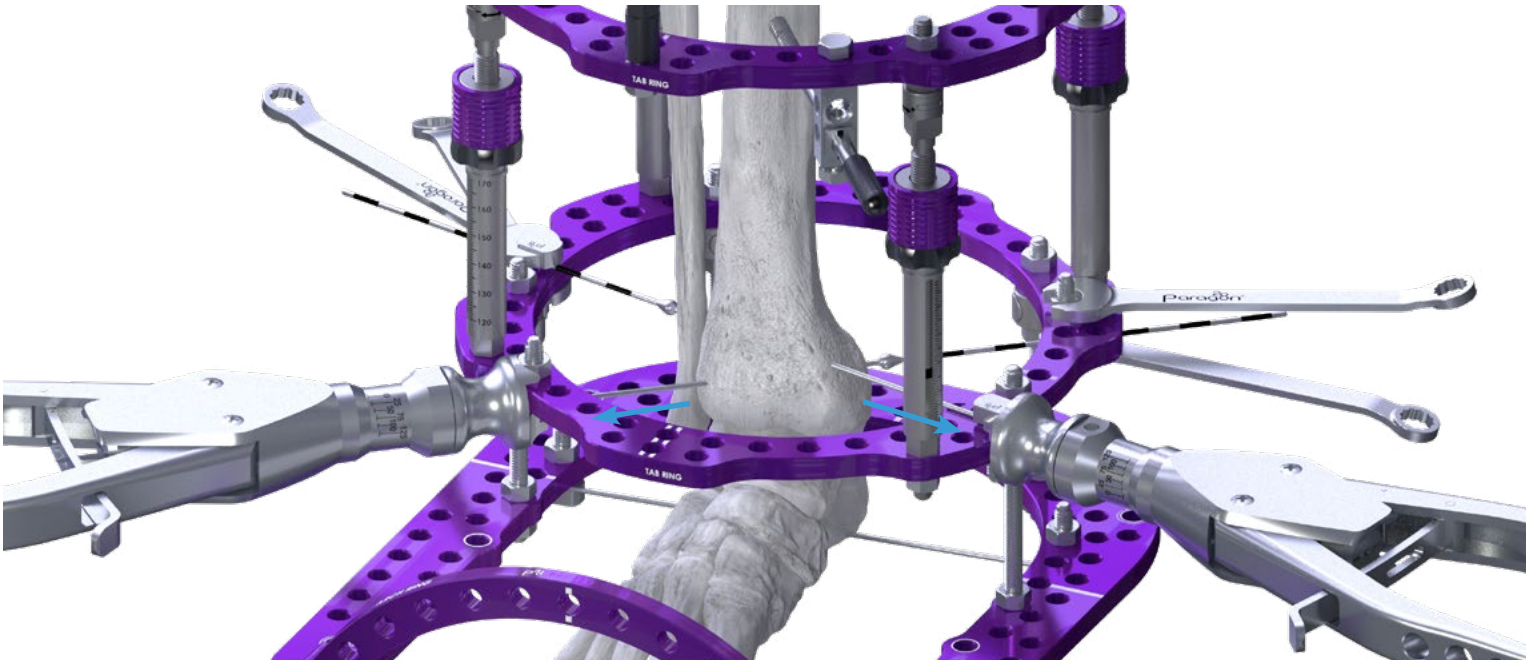
Similar to the proximal tibial ring block, each Reduction Wire should be placed in an alternating position above and below the Full Ring to avoid interference and deflection with the other Wire. Fully tighten one Wire Bolt per Wire, at this time using the provided Wrench.

CIRCULAR EXTERNAL FIXATION APPLICATION

Simultaneously tension the Reduction Wires from opposite ends until 125 kg of tension is reached.



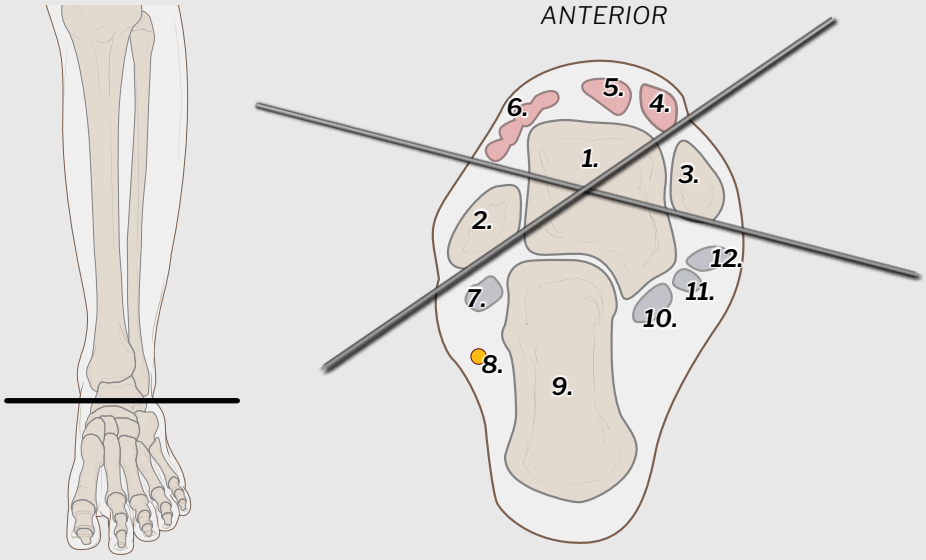
NOTE: *If using Reduction Wires, the Wire should be secured to the frame on the dashed side of the Wire. The Wire Tensioner should be placed on the non-dashed side.*



After desired tension has been achieved, fully secure the Reduction Wires to the Full Ring using the provided Wrench. The excess Wire may be bent or clipped per surgeon preference.

Distal tibial Wires are shown here to demonstrate adding stability to a static construct. Once distal tibial Wires are placed, additional compression may not be obtained using the Quick Adjust Struts in this scenario.

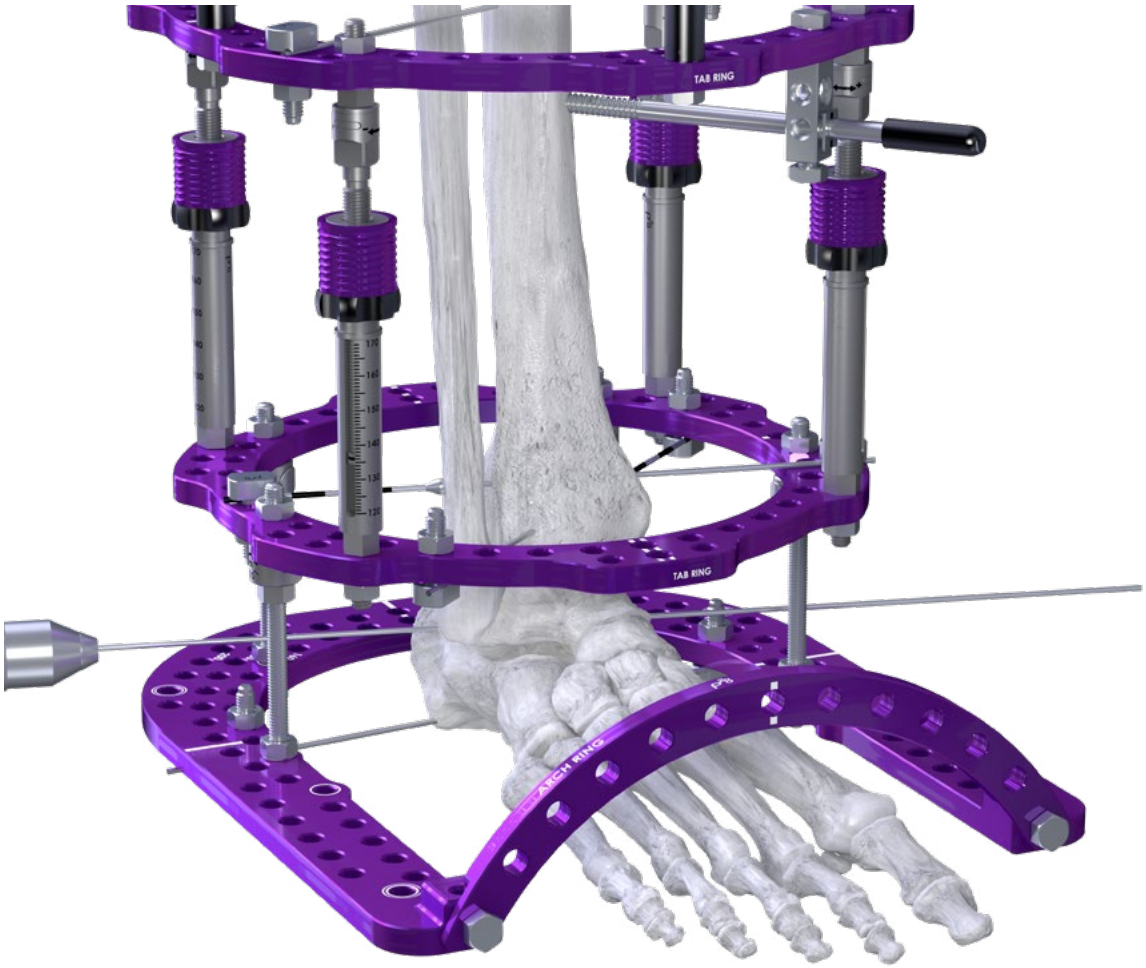
CIRCULAR EXTERNAL FIXATION APPLICATION



1. Tibia
2. Fibula
3. Medial Malleolus
4. Tibialis Anterior Muscle
5. Extensor Hallucis Muscle
6. Extensor Digitorum Longus Tendon
7. Peroneal Tendon
8. Sural Nerve
9. Calcaneus
10. Flexor Hallucis Longus Tendon
11. Flexor Digitorum Tendon
12. Tibialis Posterior Tendon

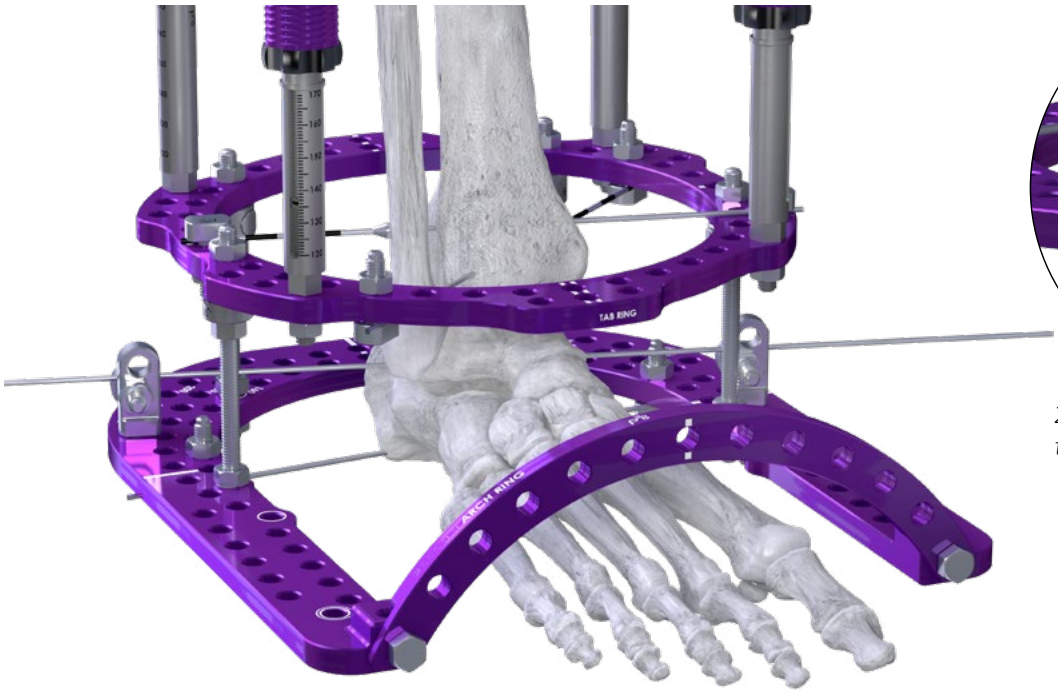
Care should be taken to avoid all major landmarks depicted above.

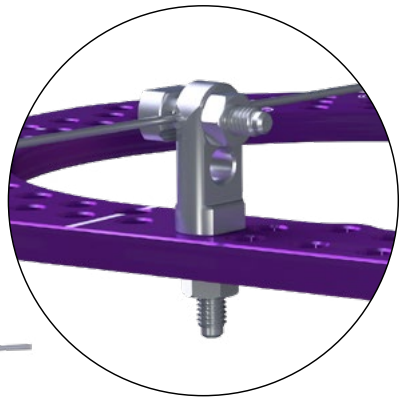
Place an additional Wire through the calcaneus from lateral to medial with a minimum of a 30° angle to the other Wire.



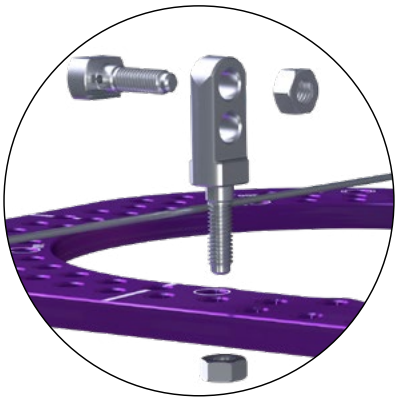
CIRCULAR EXTERNAL FIXATION APPLICATION

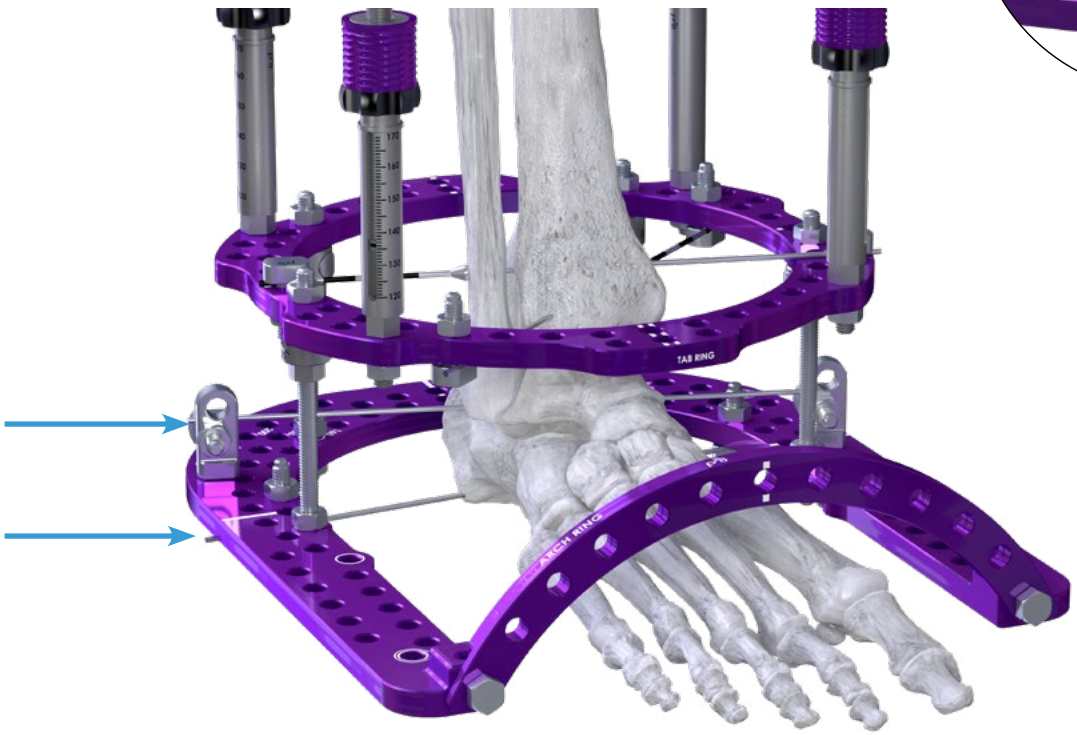
Loosely secure the calcaneal Wire with a Wire Fixation Bolt at this time. Per surgeon preference, a Post may be used to secure the Wires.





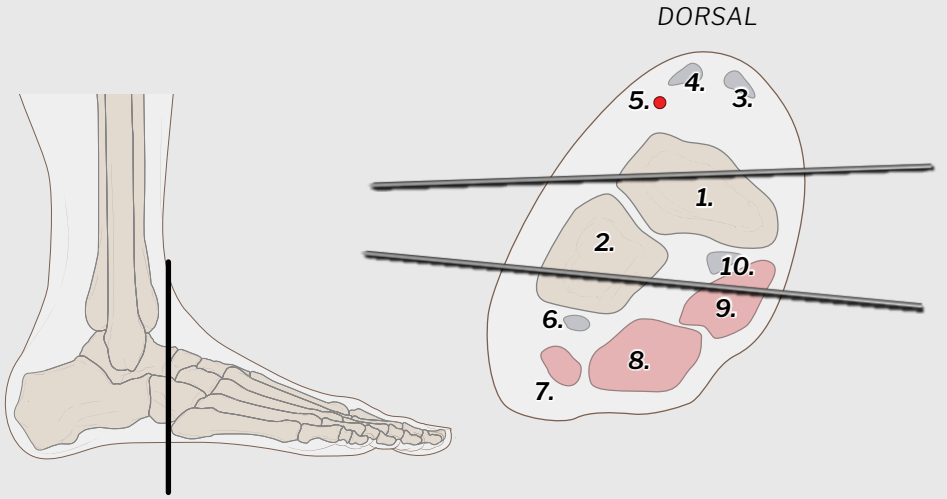
2-Hole Extension Post assembly to Wire Bolt on Foot Plate





Both calcaneal Wires should alternate in placement above and below the Foot Plate to avoid skiving and interference with the other Wire. It is recommended not to tension the calcaneal Wires until the midfoot Wires have been tensioned.

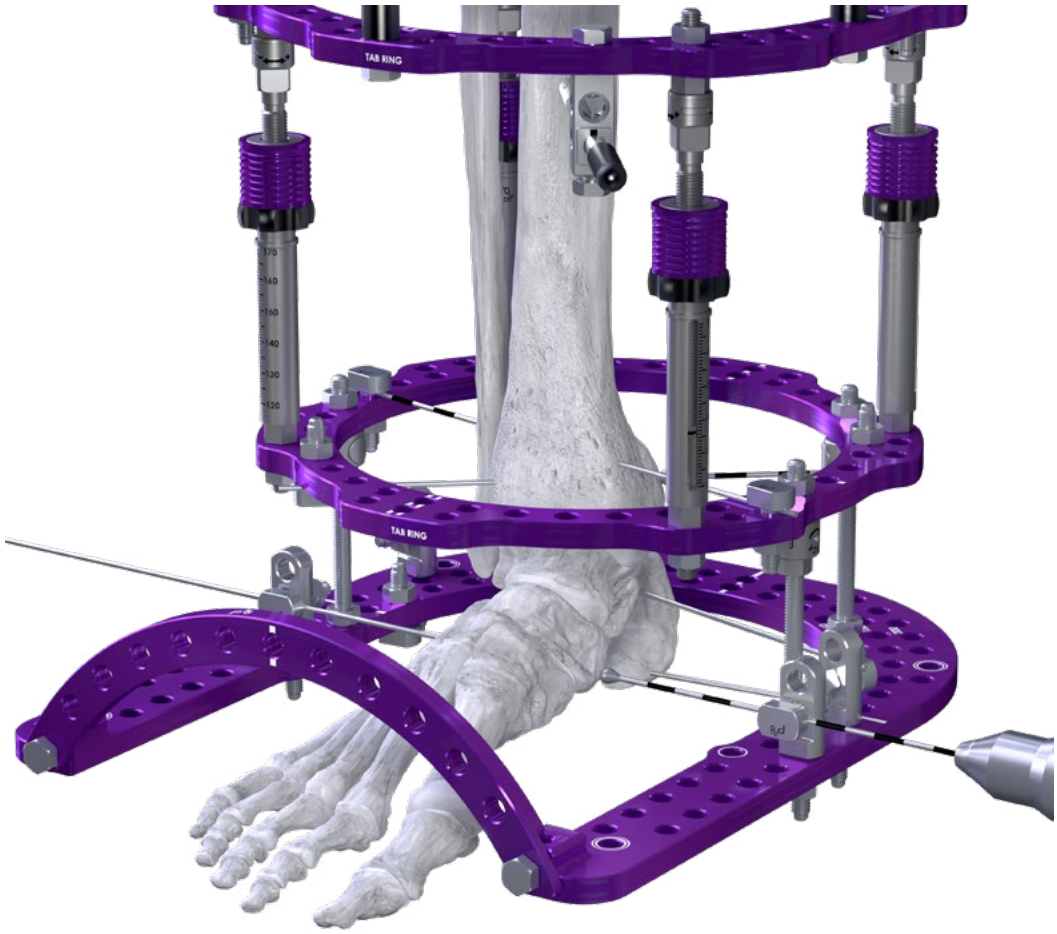
CIRCULAR EXTERNAL FIXATION APPLICATION



1. Navicular
2. Cuboid
3. Tibialis Anterior Tendon
4. Extensor Hallucis Longus Tendon
5. Dorsal Pedis Artery
6. Peroneus Longus Tendon
7. Abductor Digiti Minimus Muscle
8. Flexor Digitorum Brevis Muscle
9. Abductor Hallucis Muscle
10. Tibialis Posterior Tendon

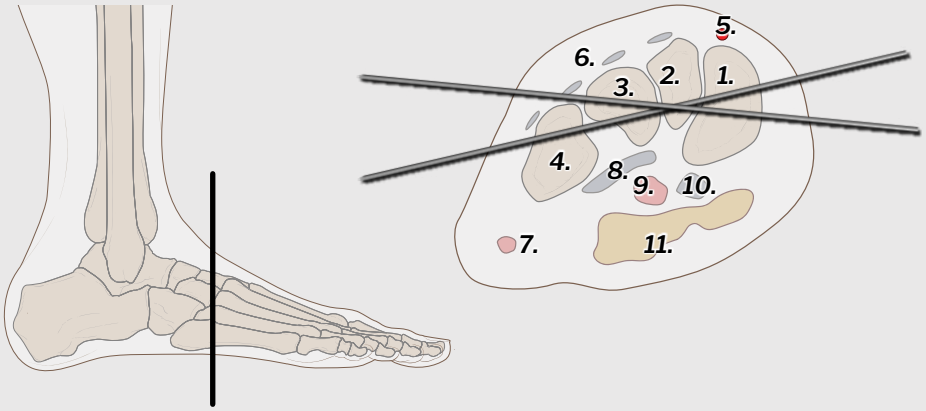
Care should be taken to avoid all major landmarks depicted above.

Place a Reduction Wire through the medial midfoot.



NOTE: *The medial Reduction Wire should aim for the middle of the navicular. In the case of soft bone, a Washer may be used.*

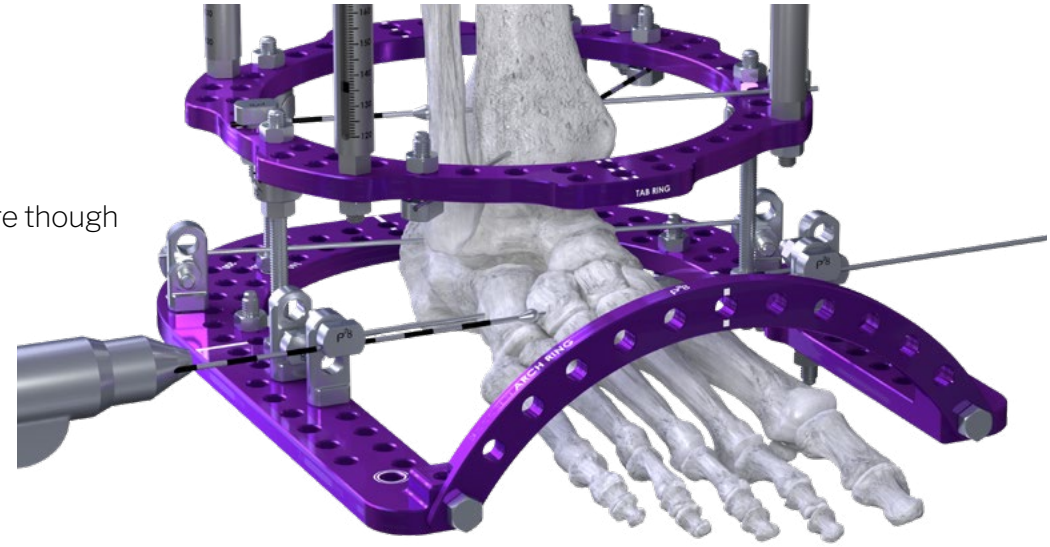
CIRCULAR EXTERNAL FIXATION APPLICATION

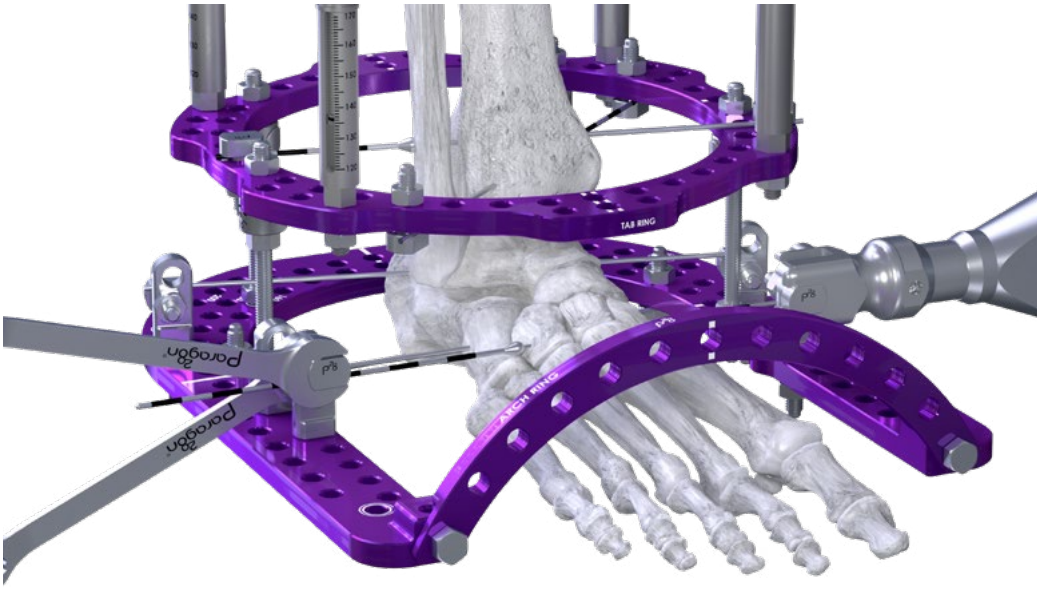


1. Medial Cuneiform
2. Intermediate Cuneiform
3. Lateral Cuneiform
4. Cuboid
5. Dorsal Pedis Artery
6. Extensor Digitorum Longus Tendons
7. Abductor Digiti Minimus Muscle
8. Peroneus Longus Tendon
9. Flexor Digitorum Brevis Muscle
10. Flexor Hallucis Longus Tendon
11. Plantar Fascia

Care should be taken to avoid all major landmarks depicted above.

Place a second Reduction Wire though the lateral midfoot.

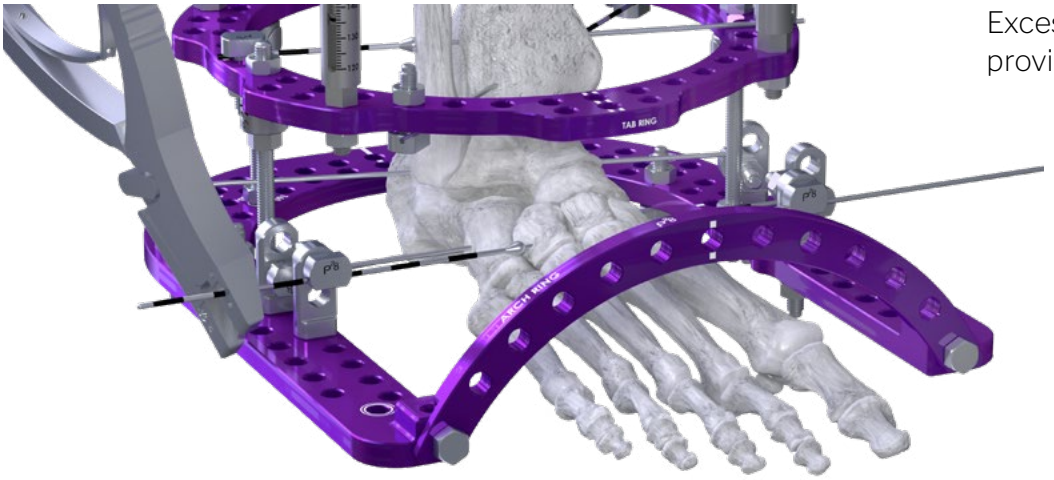




NOTE: *Forefoot Wires may be used in addition to the midfoot Wires per surgeon preference. In the instance that forefoot Wires are used, the Wires should be tensioned to 50-70 kg.*

Simultaneously tension the two midfoot Wires to 80-100 kg. This should be completed before the tensioning of the calcaneal Wires.

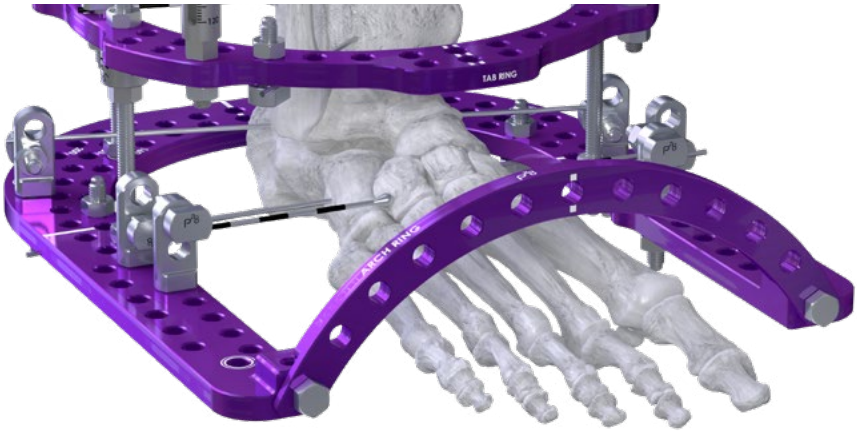
CIRCULAR EXTERNAL FIXATION APPLICATION

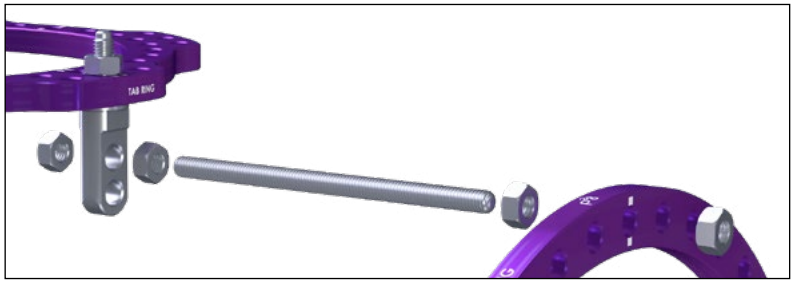


Excess Wire may be cut using the provided Wire Cutter at this time.

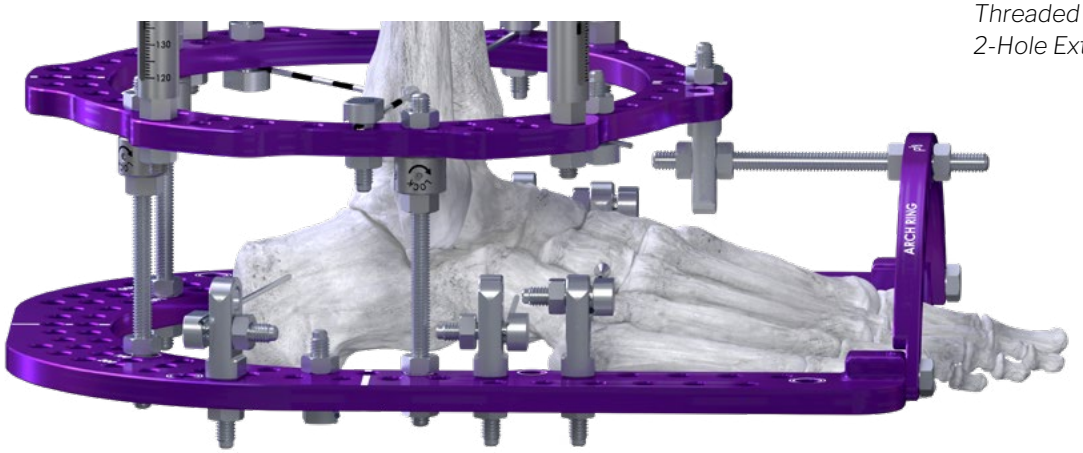
If not previously done, all Half Pins and Wires may be cut using the provided Pin Cutter/Wire Cutter.

Any additional supporting Threaded Rods or Threaded Pillars may be added per surgeon preference.





Threaded Rod assembly to Arch Ring and 2-Hole Extension Post



An additional Extension Post may be added to the anterior portion of the most distal Ring to connect the Arch Ring using a Threaded Rod. Secure the Threaded Rod using 10 mm Nuts.

CIRCULAR EXTERNAL FIXATION APPLICATION

The Strut Locking Clip is recommended to prevent any tampering or gross adjustment of the Quick Adjustment Strut postoperatively.

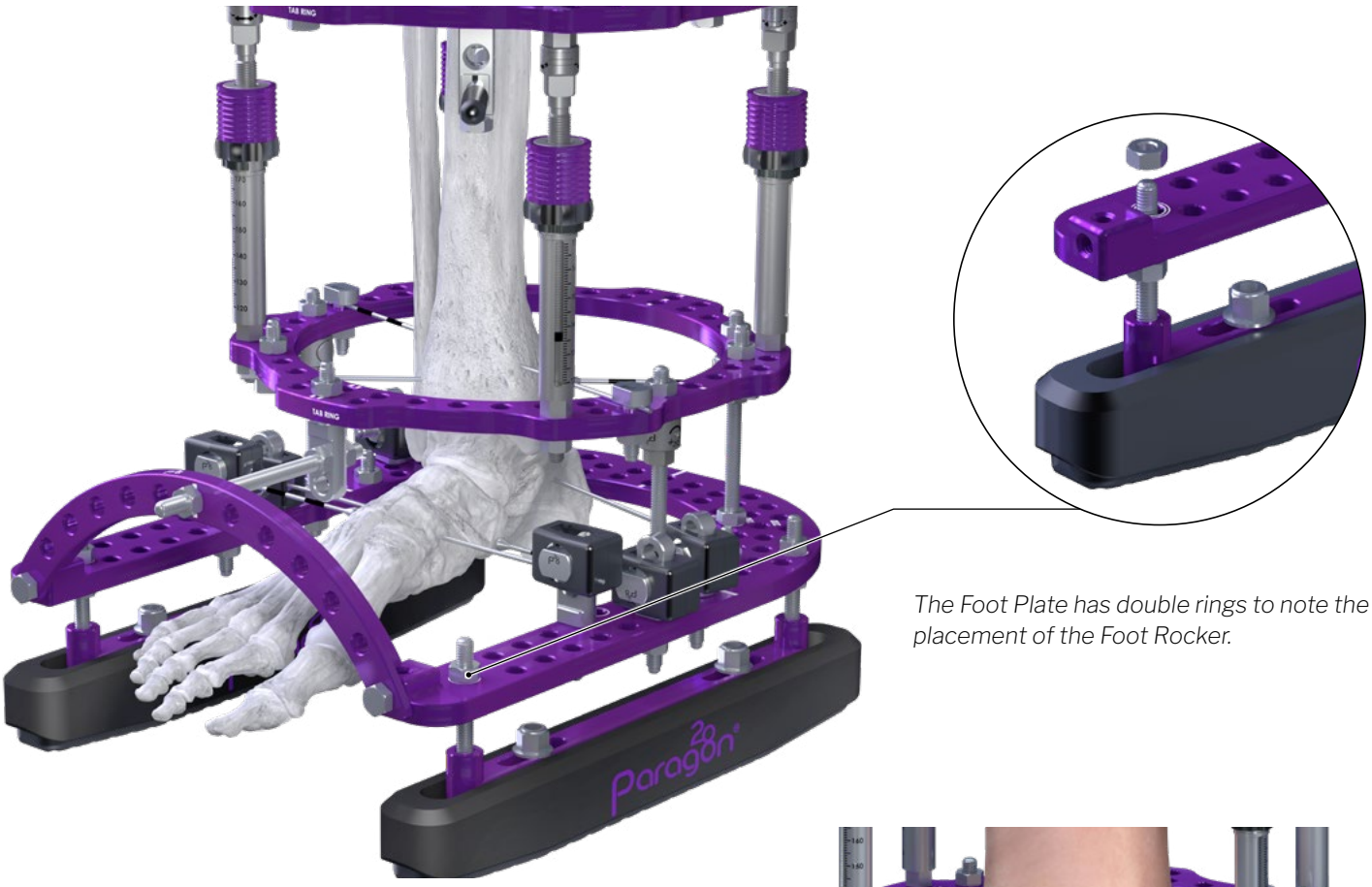
Wire Clamp Cap assembly

Ø6.0 mm protective Pin Caps and Wire Clamp Caps should be placed over the cut Half Pins and Wires, respectfully, to protect the soft tissue.

CIRCULAR EXTERNAL FIXATION APPLICATION

Per surgeon preference, a Foot Rocker Kit is provided to allow weight bearing. The Foot Rocker allows for anterior and posterior translation.

Attach the Foot Rocker to the Foot Plate through the plate holes with laser marked double Ring. Use four 10 mm M6 Bevel Nuts and secure the Foot Rocker with the provided Wrench.



The Foot Plate has double rings to note the placement of the Foot Rocker.

Anti-microbial Sponges are provided to be placed over Wires against the patient's skin to help prevent infection.

CLOSURE

Proceed to incision closure or concomitant procedures at this time. Provide a final check that all Nuts (Including Quick Release Locking Nuts) and Bolts are tightened and secured.

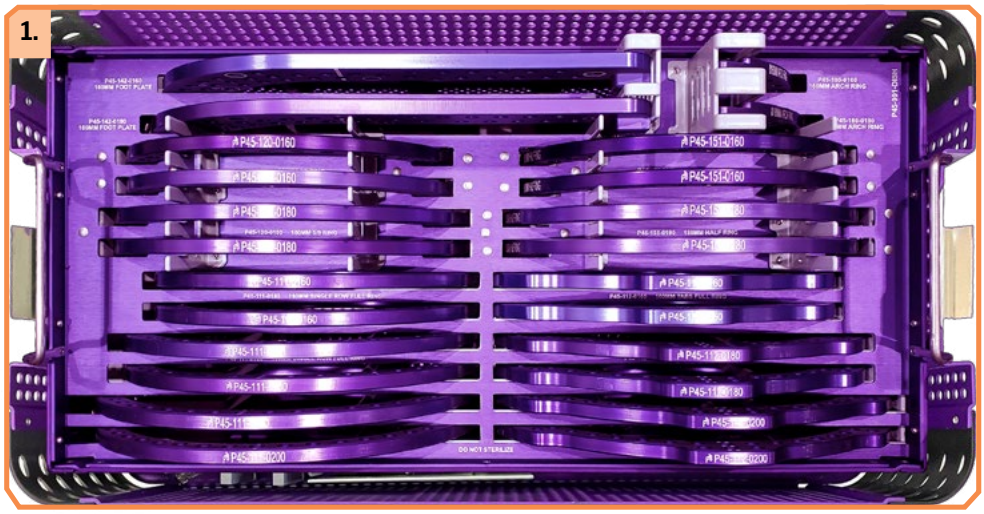
REMOVAL

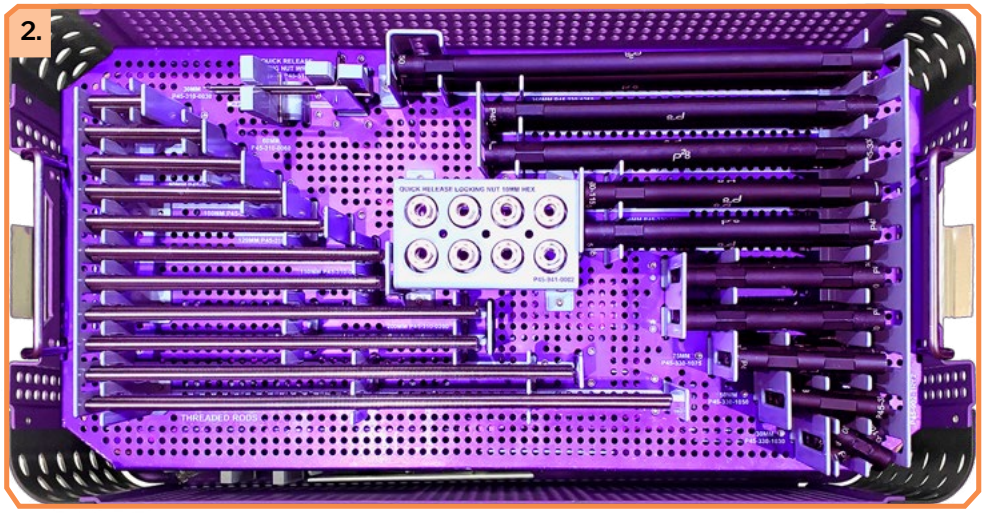
For the removal of the frame, use provided T-handle Chuck to remove any Half Pins and cut the Smooth/Reduction Wires with the provided Wire Cutter. After removal of all Wires and Half Pins, slide the frame off the patient.

MONKEY RINGS® EXTERNAL FIXATION CADDY AND CASE

1. MONKEY RINGS™ CASE 1

The Monkey Rings™ External Fixation System Case 1 contains the Single Row Full Rings, Tabbed Full Rings, 5/8 Rings, Half Rings, Arch Rings, and Foot Plates.

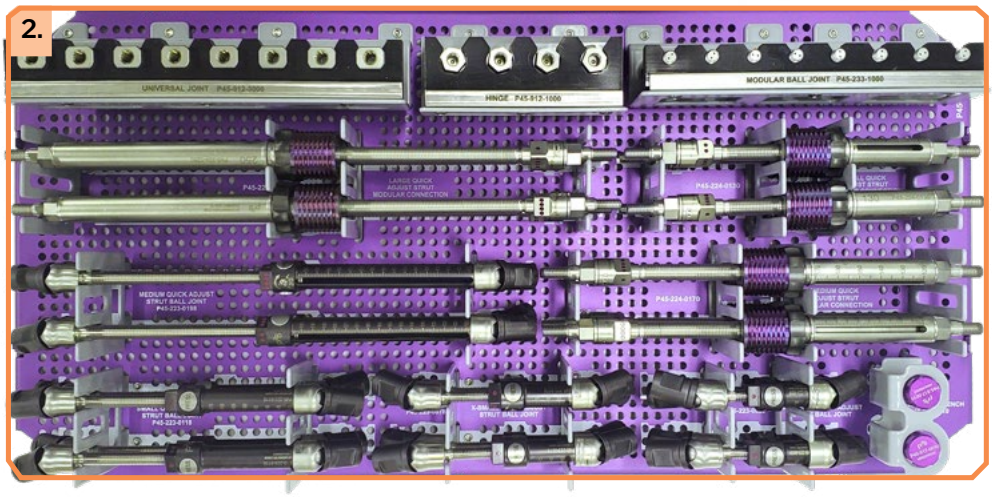




TOP TRAY

2. MONKEY RINGS™ CASE 2

The Monkey Rings™ External Fixation System Case 2 contains the Threaded Rods, Threaded Pillars, Quick Adjust Struts, Bonobo Ball Joint Struts, Hinge, Quick Release Locking Nuts, Ball Joint Strut Wrench, and Quick Release Locking Nut Wrench.



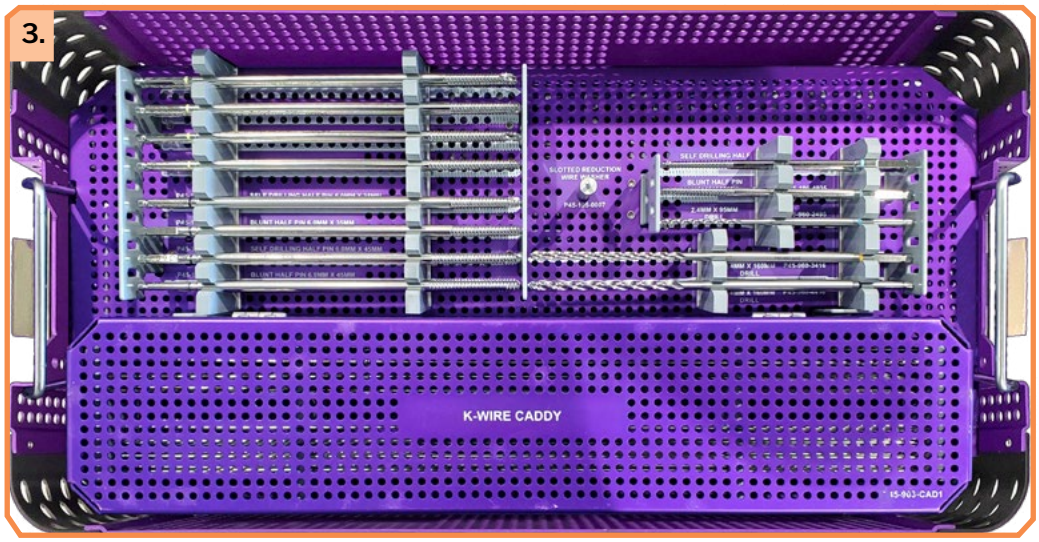
BOTTOM TRAY

*2.0 WIRE CADDY

(Available through special order).

MONKEY RINGS® EXTERNAL FIXATION CADDY AND CASE

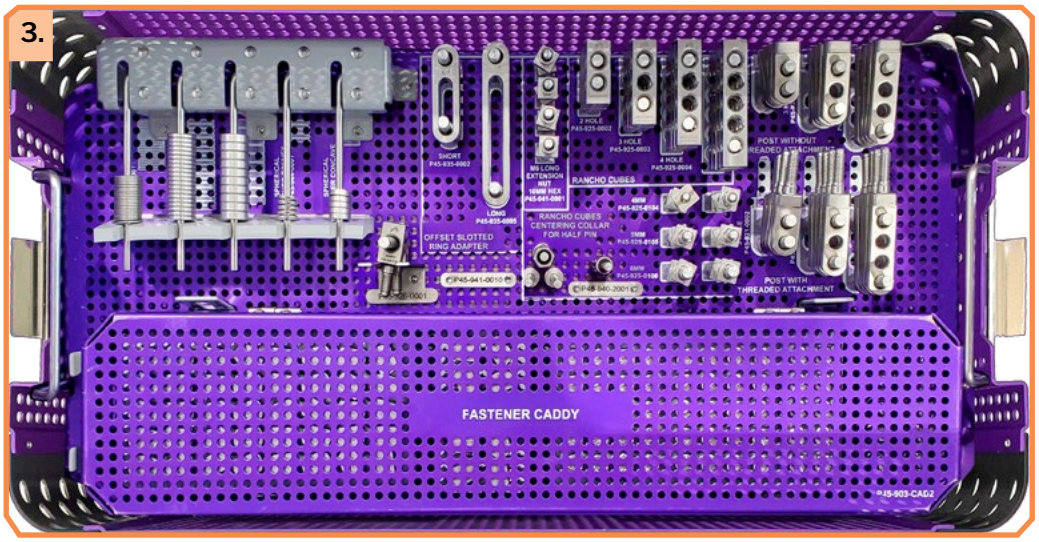
TOP TRAY

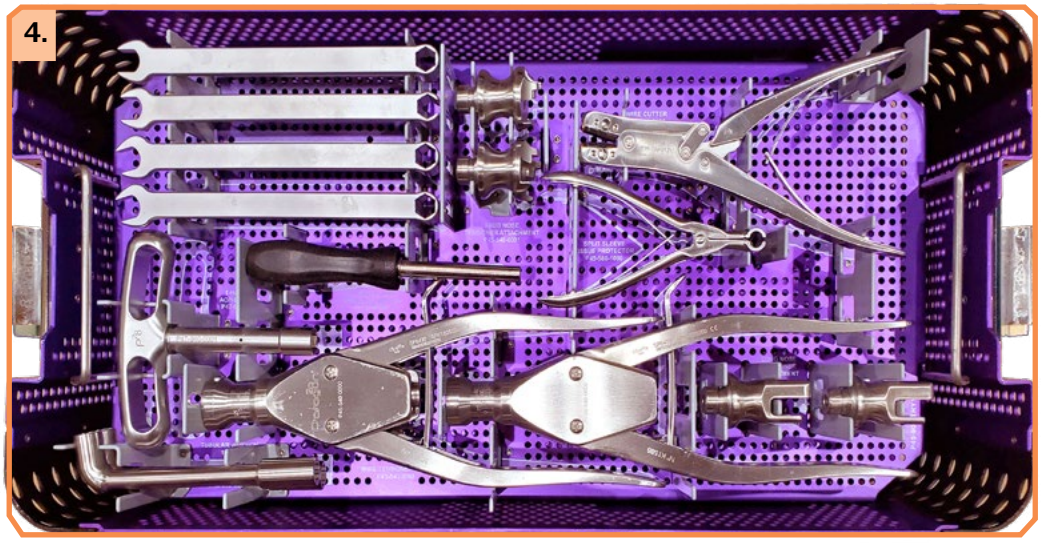


3. MONKEY RINGS™ CASE 3

The Monkey Rings™ External Fixation System Case 3 contains the Half Pins, Half Pin Drills, K-Wires, Slotted Ring Adapter, Wire Fixation Bolts, Connection Bolts, M6 Bevel Nuts, Washers, Posts, Rancho Cubes, and Universal Pin Clamps.

BOTTOM TRAY





4. MONKEY RINGS™ CASE 4

The Monkey Rings™ External Fixation System Case 4 contains the Wrenches, Wire Tensioners, T-Handle, Wire Tensioner Attachments, Tissue Protector, and Wire Cutter.

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - RINGS:

Part #	Description	Use
P45-111-0[080-220]	Full Ring - 80-220 mm, Single Row	Single-use
P45-112-0[100-220]	Full Ring - 100-220 mm, Tabs	Single-use
P45-120-0[100-220]	5/8 Ring - 100-220 mm	Single-use
P45-125-0[100-220]	5/6 Tab Ring - 120-220 mm	Single-use
P45-125-1[120-220]	5/6 Tab Closure Ring - 120-220 mm	Single-use
P45-141-0[120-220]	Short Foot Plate - 120-220 mm	Single-use
P45-142-0[120-220]	Foot Plate - 120-220 mm	Single-use
P45-151-0[080-220]	Half Ring - 80-220 mm	Single-use
P45-180-0[120-220]	Arch Ring - 120-220 mm	Single-use

*20 mm increments

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - STRUTS AND RODS

Part #	Description	Use
P45-223-0059	Quick Adjust Struts - XX-Small (45-59) (Ball Joint)	Single-use
P45-223-0078	Quick Adjust Struts - X-Small (54-78) (Ball Joint)	Single-use
P45-223-0118	Quick Adjust Struts - S (74-118) (Ball Joint)	Single-use
P45-223-0198	Quick Adjust Struts - M (114-198) (Ball Joint)	Single-use
P45-224-0250	Quick Adjust Struts - L (160-250) (Modular Connection)	Single-use
P45-224-0170	Quick Adjust Struts - M (120-170) (Modular Connection)	Single-use
P45-224-0130	Quick Adjust Struts - S (100-129) (Modular Connection)	Single-use
P45-517-0010	Ball Joint Strut Wrench	Reusable
P45-233-1000	Modular Ball Joint	Single-use
P45-912-1000	Locking Hinge	Single-use
P45-912-3000	Locking Universal Joint	Single-use
P45-941-0002	Quick Release Locking Nut, 10 mm Hex	Single-use
P45-517-0001	Quck Release Locking Nut Wrench	Reusable
P45-310-0[030-400]	Threaded Rod, 30-400 mm	Single-use
P45-330-1[030-250]	Threaded Pillar, 30-250 mm	Single-use

*See page 7 for size increments

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - HARDWARE AND PINS

Part #	Description	Use
P45-913-2001	Wire Fixation Bolt	Single-use
P45-914-0003	Connection Bolt (8mm)	Single-use
P45-914-0001	Connection Bolt (16mm)	Single-use
P45-914-0002	Connection Bolt, Long (20mm)	Single-use
P45-940-1001	M6 Bevel Nut, 10 mm Hex	Single-use
P45-940-2001	M6 Nylon Nut, 10 mm Hex	Single-use
P45-941-0001	M6 Long Extnetion Nut, Compresion/Distraction, 10mm Hex	Single-use

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - HARDWARE AND PINS

Part #	Description	Use
P45-941-0010	M6 Close Encounter Nut, 10mm Hex	Single-use
P45-943-0001	Washer, 1mm	Single-use
P45-943-0002	Washer, 2mm	Single-use
P45-943-0004	Washer, 4mm	Single-use
P45-944-0001	Spherical Washer, Convex	Single-use
P45-944-0002	Spherical Washer, Concave	Single-use
P45-970-2000	Universal Pin Clamp	Single-use
P45-920-000[1-4]	Post, without Threaded Attachment	Single-use
P45-921-000[2-4]	Post, with Threaded Attachment	Single-use
P45-926-0001	Rancho Cube, 1 Hole, with Threaded Attachment	Single-use
P45-925-000[2-5]	Rancho Cube	Single-use
P45-925-010[4-6]	Rancho Cube, Centering Collar	Single-use
P45-935-0002	Offset Slotted Ring Adapter, Short	Single-use
P45-935-0005	Offset Slotted Ring Adapter, Long	Single-use
P45-191-4035	Half Pin, Self Drilling, Ø4mm x 35mm, 95mm Shank Length	Single-use
P45-196-4035	Half Pin, Blunt, Ø4mm x 35mm, 95mm Shank Length	Single-use
P45-191-5035	Half Pin, Self Drilling, Ø5.0mm X 35mm, 160mm SHANK LENGTH	Single-use
P45-196-5035	Half Pin, Blunt, Ø5.0mm X 35mm, 160mm SHANK LENGTH	Single-use
P45-191-5045	Half Pin, Self Drilling, Ø5.0mm X 45mm, 160mm SHANK LENGTH	Single-use
P45-196-5045	Half Pin, Blunt, Ø5.0mm X 45mm, 160mm SHANK LENGTH	Single-use
P45-191-6035	Half Pin, Self Drilling, Ø6.0mm X 35mm, 160mm SHANK LENGTH	Single-use
P45-196-6035	Half Pin, Blunt, Ø6.0mm X 35mm, 160mm SHANK LENGTH	Single-use
P45-191-6045	Half Pin, Self Drilling, Ø6.0mm X 45mm, 160mm SHANK LENGTH	Single-use
P45-196-6045	Half Pin, Blunt, Ø6.0mm X 45mm, 160mm SHANK LENGTH	Single-use
P45-194-1840	Wire, Ø1.8 x 400 Smooth, Half Point	Single-use
P45-195-1840	Wire, Ø1.8 x 400 Reduction, Half Point	Single-use
P45-960-2495	Ø2.4mm x 95mm Drill for Ø4.0 Half Pins	Single-use
P45-960-3416	Ø3.4mm x 160mm Drill for Ø5.0 Half Pins	Single-use
P45-960-4416	Ø4.4mm x 160mm Drill for Ø6.0 Half Pins	Single-use

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - TOOLS:

Part #	Description	Use
P45-513-0001	Angled Socket Wrench, 10mm	Reusable
P45-513-0002	Slotted Straight Wrench, 10mm	Reusable
P45-513-0003	Closed Straight Wrench, 10mm	Reusable
P45-513-0004	Tubular Wrench, 10mm	Reusable
P45-520-2000	Pin Cutter	Reusable
P99-150-0121	Wire Cutter	Reusable
P45-540-0000	Wire Tensioner Body	Reusable
P45-540-0001	Tensioner, Snub Nose Attachment	Reusable

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - TOOLS:

Part #	Description	Use
P45-540-0002	Tensioner, Long Nose Attachment	Reusable
P47-940-0001	T-handle, AO/10mm Hex	Reusable
P45-580-1000	Split Tissue Protector Sleeve, 6.0	Reusable
P45-550-0001	Universal T Chuck	Reusable
P45-962-[4-6]000	Drill Guide for Half Pin Drill	Reusable
P45-513-0010	Ratcheting Wrench, 10 mm	Reusable
P45-540-0003	Long Nose Tensioner Tip	Reusable
P45-192-1023	2.3mm x 230mm Steinman Pin	Single-use
P45-192-1032	3.2mm x 230mm Steinman Pin	Single-use
P45-193-4030	4.0mm x230mm Steinman Pin	Single-use

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - BLACK BOX ITEMS:

Part #	Description	Use
P45-170-1000	Foot Rocker Kit	Single-use
P45-170-3000	Short Foot Rocker	Single-use
P45-198-1000	Wire Clamp Caps	Single-use
P45-198-4000	Protective Cap, 4.0	Single-use
P45-198-5000	Protective Cap, 5.0	Single-use
P45-198-6000	Protective Cap, 6.0	Single-use
P45-199-4035-S	Half Pin, Self Drilling, Ø4.0mm x 34mm, 120mm SHANK LENGTH, HA COATED	Single-use
P45-199-5030-S	Half Pin, Self Drilling, Ø5.0mm X 30mm, 130mm SHANK LENGTH, HA COATED	Single-use
P45-199-5035-S	Half Pin, Self Drilling, Ø5.0mm X 35mm, 180mm SHANK LENGTH, HA COATED	Single-use
P45-199-5045-S	Half Pin, Self Drilling, Ø5.0mm X 50mm, 180mm SHANK LENGTH, HA COATED	Single-use
P45-199-6030-S	Half Pin, Self Drilling, Ø6.0mm X 30mm, 180mm SHANK LENGTH, HA COATED	Single-use
P45-199-6035-S	Half Pin, Self Drilling, Ø6.0mm X 35mm, 180mm SHANK LENGTH, HA COATED	Single-use
P45-199-6045-S	Half Pin, Self Drilling, Ø6.0mm X 50mm, 180mm SHANK LENGTH, HA COATED	Single-use
P45-960-3219-S	Ø3.2mm x 195mm Drill for HA Half Pins	Single-use
P45-965-4000-S	Ø4.0mm Half Pin Quick Connect	Single-use
P45-965-5000-S	Ø5.0mm Half Pin Quick Connect	Single-use
P45-965-6000-S	Ø6.0mm Half Pin Quick Connect	Single-use
P45-600-1000-S	Infection Shielding Pin and Wire Site Protective Sponges	Single-use
P45-610-1000	Pin and Wire Site Protective Sponge Fasteners	Single-use
P47-950-0001	Wrench, 10 mm	Reusable

MONKEY RINGS CIRCULAR EXTERNAL FIXATION - SPECIALTY WIRES:

Part #	Description	Use
P45-194-1850	Wire, 1.8 x 500 Smooth, Half Point	Single-use
P45-195-1850	Wire, 1.8 x 500 Reduction, Half Point	Single-use
P45-194-2050	Wire, 2.0 x 500 Smooth, Half Point	Single-use
P45-195-2050	Wire, 2.0 x 500 Reduction, Half Point	Single-use
P45-194-2040	Wire, 2.0 x 400 Smooth, Half Point	Single-use
P45-195-2040	Wire, 2.0 x 400 Reduction, Half Point	Single-use
P45-194-2140	Wire, 2.0 x 400 Smooth, Half Point, Titanium	Single-use
P45-195-2140	Wire, 2.0 x 400 Reduction, Half Point, Titanium	Single-use

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE

The Monkey Rings™ External Fixation System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis, infected union, non-union, or malunion of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity (e.g. orthoplastic surgery)
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures
- Bone transport

The Monkey Rings™ External Fixation System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle
- Lisfranc dislocations
- Ankle distraction (arthrodiastasis)
- Septic fusion

CONTRAINDICATIONS

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.

In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic, and patients with a history of infection
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the devices
- Osteopathies with reduced bone substance that could affect the function of the devices
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment. The risk of breakage of a fixation device is greater in older patients with mental deficiency, alcoholics or drug addicts or patients who, for other reasons, may ignore the necessary restrictions and precautions to be observed while using the device.
- Known or suspected sensitivity to device materials
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or device failure can occur

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation, migration, subluxation, fracture of the device, or premature loss of fixation with the bone which may result in nerve and soft tissue damage
- Delayed union, non-union, or malunion resulting in breakage of the construct. If healing is delayed, or does not occur, the construct may eventually break due to the increased loading.
- Acute post-operative wound infections and late infections with possible sepsis and osteomyelitis, including chronic drainage of the Schanze screw sites following removal of the device.
- Migration, subluxation of the implant with resulting reduction in range of movement
- Thrombosis or embolism
- Avascular necrosis
- Tissue necrosis, wound hematoma and delayed wound healing
- Excessive surgical bleeding
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

- Shortening of the affected bone/fracture site.
- Bone loss or reduced bone density due to a reduction in the tension applied to the bone.
- Fractures resulting from unilateral joint loading
- Edema or possible compartmental syndrome.
- Premature bone callus consolidation during distraction.
- Possible tension affecting the soft tissues and/or the fixation during manipulation of the callus (e.g. corrections of deformities and/or elongation).
- Fracture of regenerated bone, or at the Schanze screw holes, following removal of the device.
- Bone damage due to erroneous Schanze screw selection.
- Bone deformities or talipes equinus.
- The persistence or recurrence of the initial condition subject to treatment.
- Abnormal growth cartilage development in skeletally immature patients.
- Pressure on the skin caused by external components when the free space is insufficient.
- Secondary bony sequestration due to rapid perforation of the cortex with accumulation of heat and bone necrosis.
- Nerve or vascular damage following the insertion of Schanze screws or wires.

All possible complications listed here are not typical of Paragon 28® Inc. products but are in principle observed with any implant. Promptly inform Paragon 28® in the event that complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent non-compliant patient behavior.

WARNINGS AND PRECAUTIONS

- The patient must be informed that a second minor surgery for the removal of the fixation system is required.
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- The implants and guide wires are intended for single use only.
- Guide wires and Schanze screws are to be treated as sharps.
- Do not reuse single use devices. Reuse of single-use external fixators may lead to reduced biomechanical properties and/or fatigue breakage of the devices.
- Do not use other manufacturer's instruments or implants in conjunction with the Monkey Rings™ External Fixation System.

MR SAFETY INFORMATION

The Monkey Rings™ External Fixation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Monkey Rings™ External Fixation System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

MONKEY RINGS

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P45-STG-0001 RevH [2024-11-27]

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DISCLAIMER

The purpose of the Monkey Rings™ Circular External Fixation System Surgical Technique Guide is to demonstrate the optionality and functionality of the Monkey Rings™ Circular External Fixation System implants and instrumentation. Although variations in placement and use of the Monkey Rings™ Circular 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 Rings™ Circular 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.