stryker

Hoffmann® LRF Gradual Correction

Operative technique

Hoffmann LRF
Gradual Correction

Contents

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to performing your first surgery.

WARNING

Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1). All non-sterile devices must be cleaned and sterilized before use.

WARNING

Multicomponent instruments must be disassembled for cleaning. Please refer to the corresponding assembly/ disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects, contraindications, warnings and precautions.

WARNING

- The surgeon must warn patients of surgical risks, and make them aware of possible adverse effects.
- The patient should be warned that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma, malunion or nonunion.
- The surgeon must warn the patient that the device has a finite expected service life and may need to be removed at some time in the future.

NOTICE

This operative guide contains information specific to the Hoffmann LRF Gradual Correction System hardware. For a complete overview of the entire Hoffmann LRF System, it is recommended that the user also references the Hoffmann LRF Circular External Fixation operative technique (H-ST-1), Hoffmann LRF bone transport operative technique (H-ST-31), the Hoffmann LRF Hexapod operative technique (H-ST-34) the Patient Guide for External Fixation (H-PG-1), the Hoffmann LRF Hexapod Hole Offset Guide (H-ADI-1), and the Hoffmann LRF Web Application user manual (H-IFU-2).

Indications & contraindications

Indications for use (Europe and other countries)

The Hoffmann LRF System is indicated in (upper and lower) extremities 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 or non-union of long bones.
- Limb lengthening by epiphyseal or metaphyseal distraction.
- Correction of bony or soft tissue deformity.
- Correction of segmental bony or soft tissue defects.
- Joint arthrodesis.
- Bone transport.
- Osteotomy.
- Revision procedure where other treatments or devices have been unsuccessful.
- Bone reconstruction procedures.
- Foot Fusion.
- Charcot foot reconstruction.
- Lisfranc dislocations.

Indications for use (United States and Canada)

The Hoffmann LRF System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resultedin 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 or non-union of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of communicated intra-articular fractures of the distal radius
- Bone transport

The Hoffmann LRF 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
- Lisfranc dislocations

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.

Conditions presenting an increased risk of failure include:

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.
- Previous history of infections.
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Malignancy in the fracture area.
- Mental, physical or neurological conditions which may impair the patient's ability to cooperate with the postoperative regimen.

Indications & contraindications

Precautions

Information for patient.

CAUTION

Surgeons must instruct the patients to report any unusual changes of the operated site to their physician. The surgeon(s) should immediately evaluate the patient if a change at the fracture site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for reduced activity levels, and / or possible revision surgery in order to aid fracture healing.

CAUTION

The surgeon should discuss all physical and psychological limitations inherent in the use of external fracture fixation appliances with the patient. Particular attention should be given to premature weight bearing, activity levels and the necessity for periodic medical follow-up.

WARNING

The Hoffmann LRF System is MR Unsafe.

WARNING

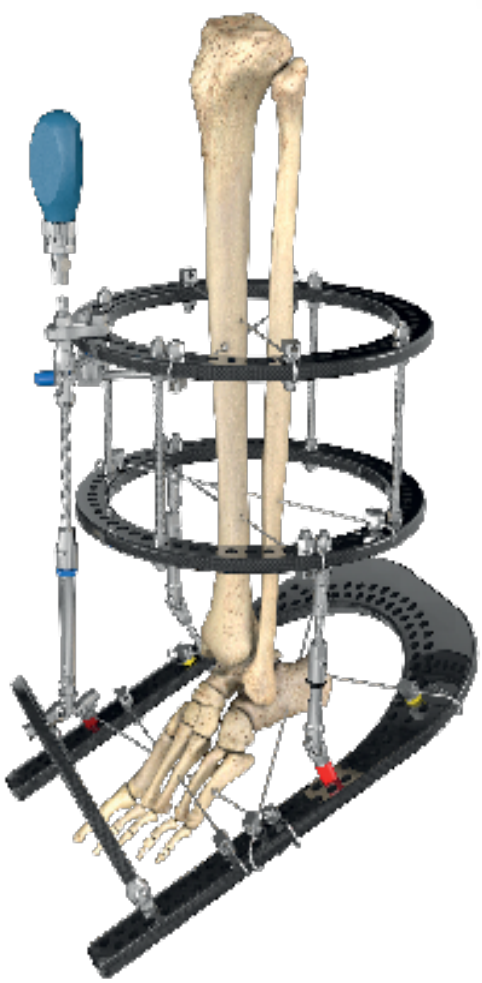
Single use devices cannot be reused, as they are not designed to perform as intended after the first usage. Mechanical, physical or chemical properties may be compromised after first usage. In this case, the safety and performance of the devices is not supported by the manufacturer, compliance to relevant specifications cannot be ensured. External fixator devices have been designed for single patient use. Reuse of single-use external fixators may lead to reduced biomechanical properties and/or fatigue breakage of the devices. Do not reuse single-use external fixator components. Please refer to the device label to identify single or multiple use and / or re-sterilization release.

WARNING

Take caution not to exert excessive tightening force on frame components as this may also compromise component integrity and performance.

Introduction

Hoffmann LRF Gradual Correction introduces telescopic hinge struts and telescopic motor struts for procedures requiring gradual corrective adjustments.

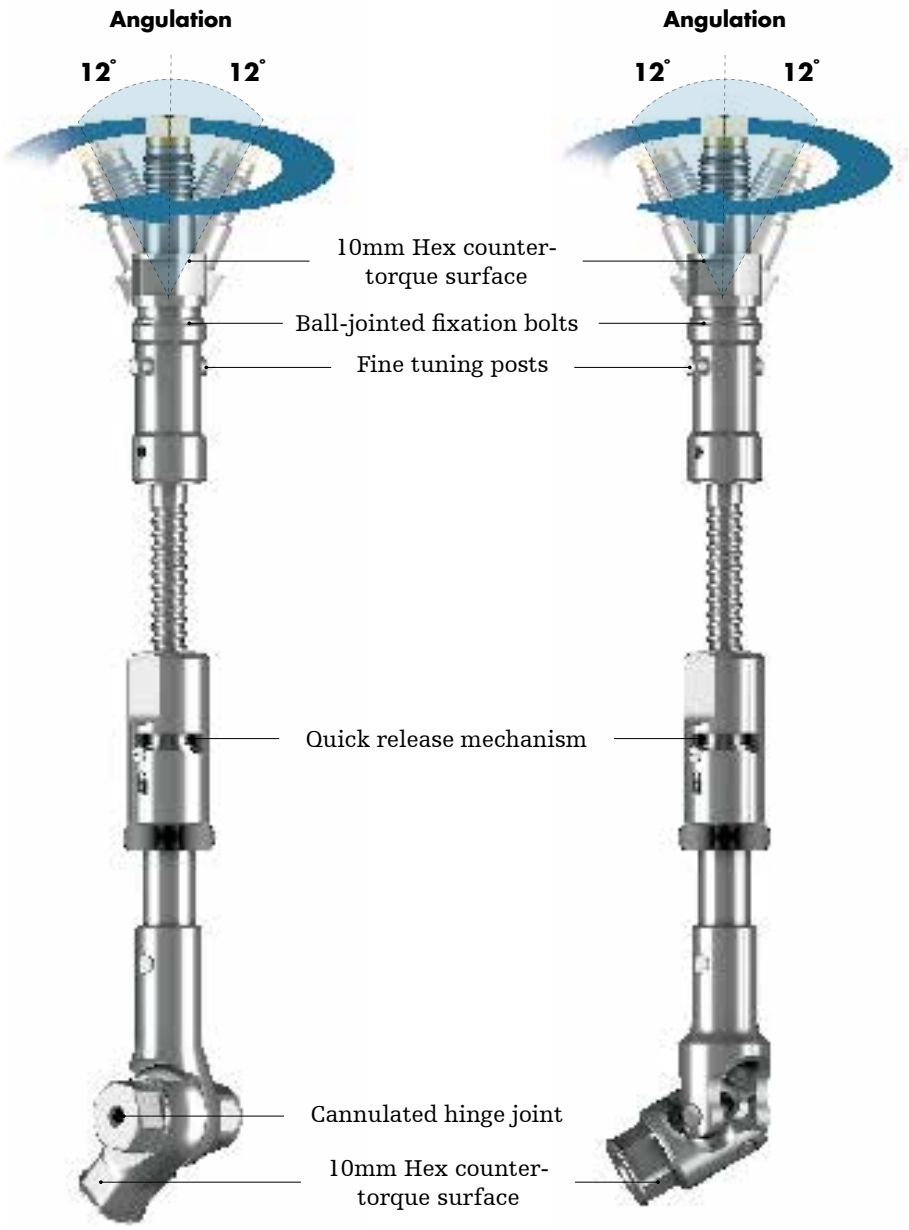


Key components

Hinged telescopic struts

Hinged telescopic struts are designed to align and pivot around a specified axis of rotation. This is accomplished via universal hinged couplings integrated into the telescopic strut's design.

- Quick release mechanism allows for rapid gross length adjustment
- Ball-jointed fixation bolts allow the struts to be mounted to rings that are not parallel or of different diameters
- Length of the strut can be fine tuned by rotating the quick release mechanism relative to threaded portion of the strut (one full revolution represents 2mm of travel)
- Adjustable from 125-150mm in length ring-to-ring



Hinged telescopic strut constrained

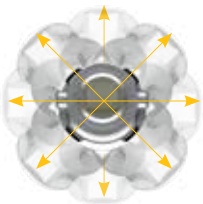
Hinged telescopic strut unconstrained

Quick release safety nut

⚠CAUTION

To avoid inadvertent disassembly of the quick release mechanism, do not loosen the colored safety nut beyond the etched line. If the colored safety nut is accidentally loosened beyond the etched line and the mechanism disassembles, simply push the colored safety nut and spring back into the quick release body and re-tighten the nut with clockwise turns until the assembly reengages.

Lockable, uniplanar range of motion



Polyaxial range of motion

Key components

Hinged telescopic struts: fine tuning length

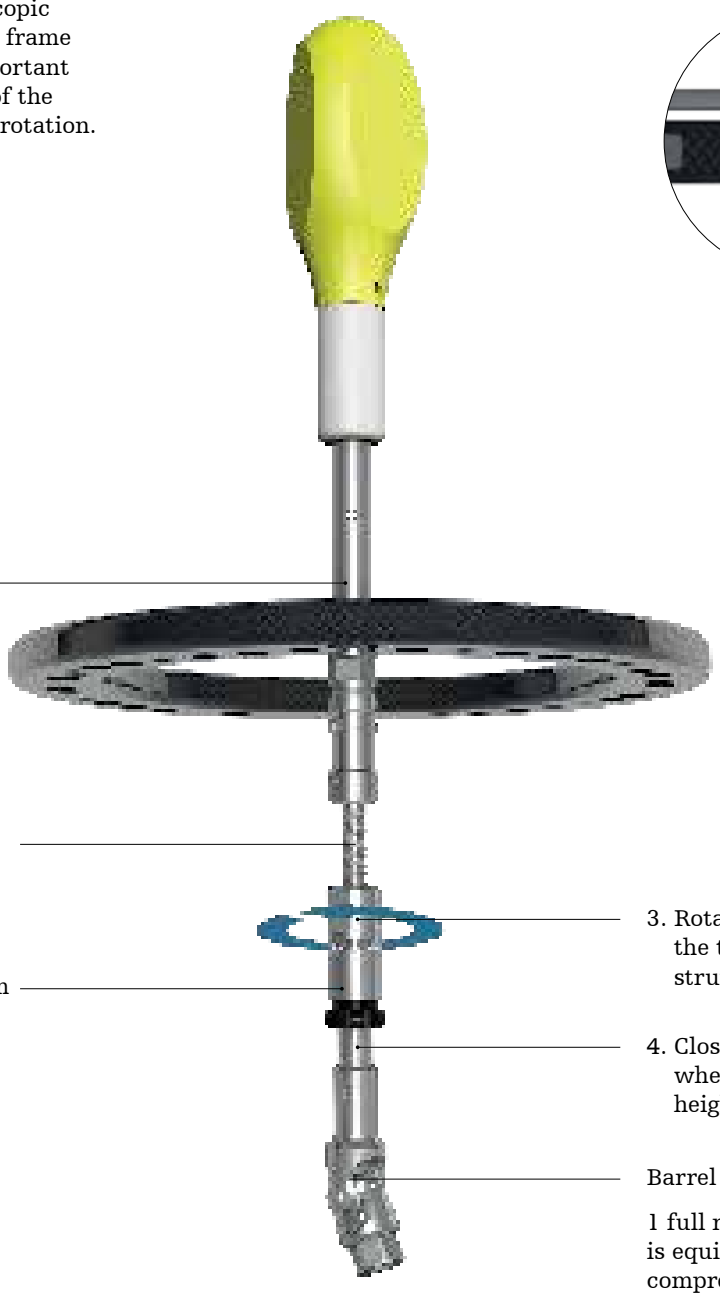
Procedure when struts are attached to 1 ring only:

The length of the Hinged Telescopic Struts can be fine tuned during frame assembly. This sequence is important when aligning the hinged end of the strut with the specified axis of rotation.

CAUTION

Only loosen square drive enough lose resistance. Over- loosening square drive may disassemble and/ or damage the strut.

Before making any ball joint adjustments, ensure that the ball joint end of the strut is securely attached to the ring with connecting nut.



2. Tighten ball joint at the threaded end of strut.

Threaded end of strut

1. Lock quick release mechanism by aligning the pin in the locked padlock position.

3. Rotate strut barrel around the threaded portion of the strut to adjust length.

4. Close the colored safety wheel once desired frame height is achieved.

Barrel end of strut.

1 full revolution of the strut is equivalent to 2mm of compression or distraction.

CAUTION

Flats on quick release are for finger adjustment only. Attempting to rotate with a wrench or pliers may damage the strut.

Key components

Hinged telescopic struts: Fine tuning length

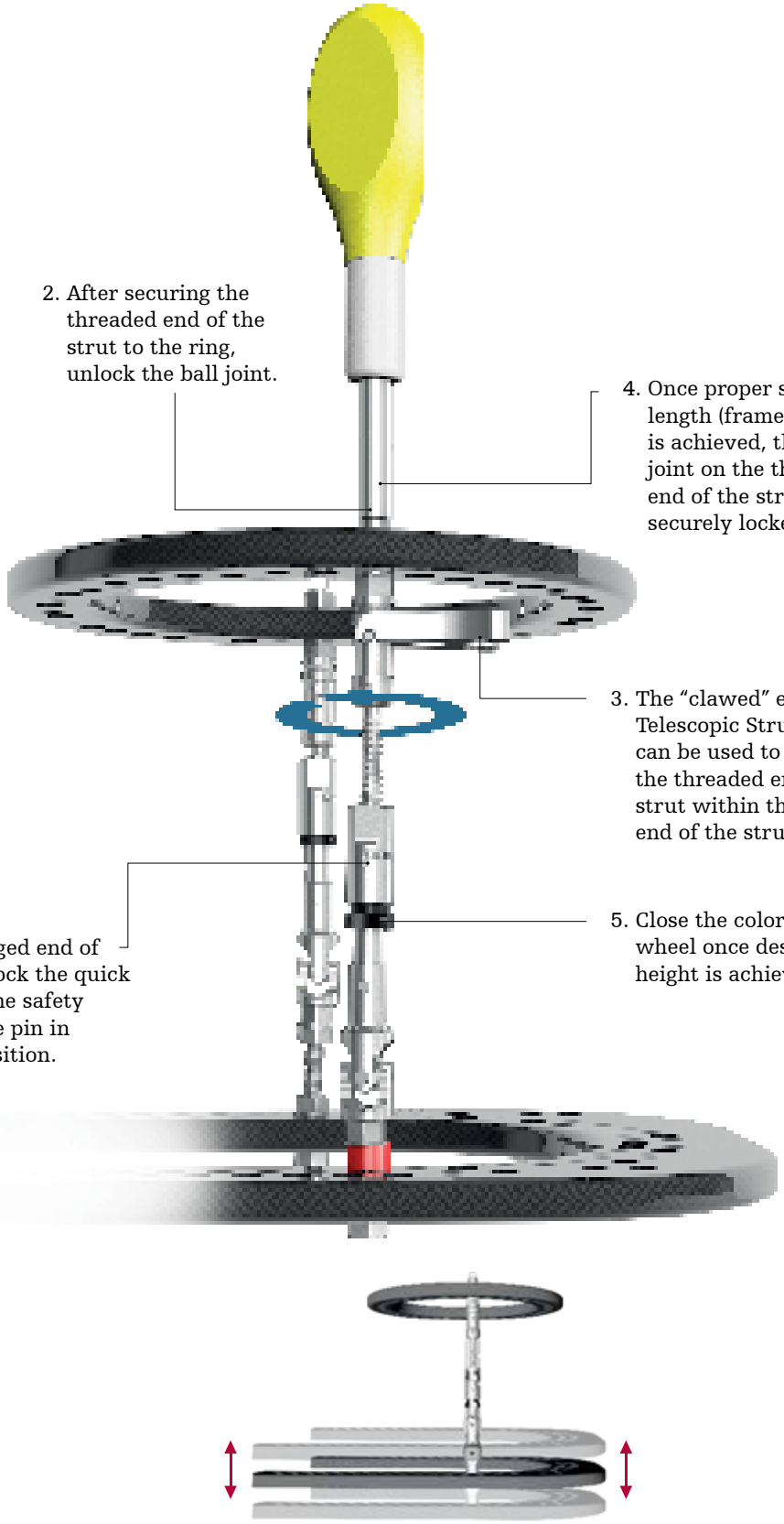
Procedure when struts are attached between two 2 rings:

If the hinged end of the strut is already attached to the ring, the length of the strut can be finely adjusted by rotating the ball-jointed end of the strut.

Before making any length adjustments, ensure that both ends of the strut are securely attached to the rings.

⚠CAUTION

Only loosen square drive enough lose resistance. Over- loosening square drive may disassemble and/ or damage the strut.



2. After securing the threaded end of the strut to the ring, unlock the ball joint.

4. Once proper strut length (frame height) is achieved, the ball joint on the threaded end of the strut is securely locked.

3. The “clawed” end of the Telescopic Strut Wrench can be used to rotate the threaded end of the strut within the barrel end of the strut.

5. Close the colored safety wheel once desired frame height is achieved.

1. After securing the hinged end of the strut to the ring, lock the quick release by loosening the safety wheel and aligning the pin in the locked padlock position.

⚠CAUTION

Flats on all quick release mechanisms are for finger adjustment only. Attempting to rotate with a wrench or pliers may damage the strut.

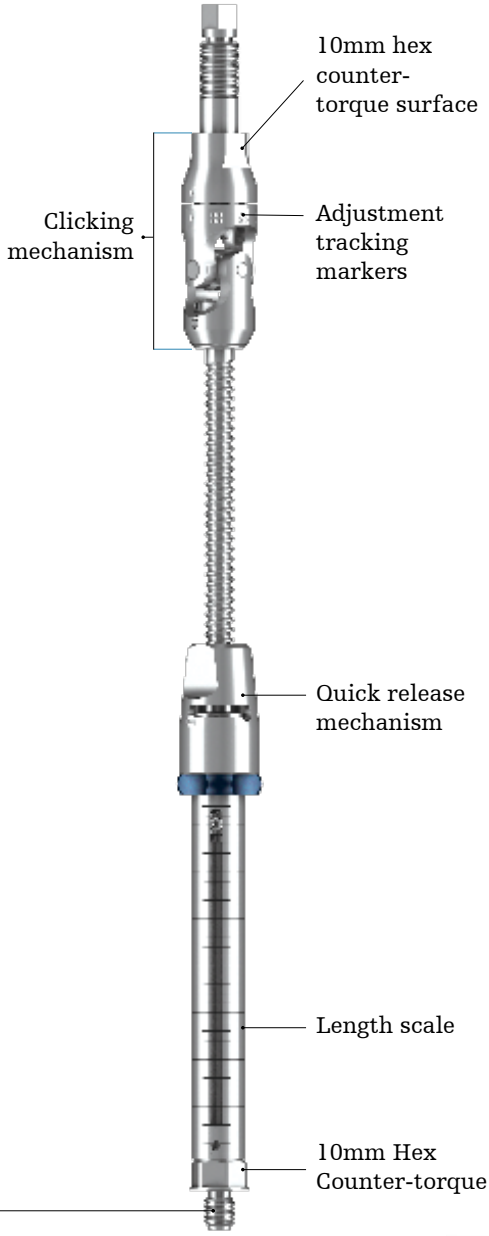
Take caution not to unintentionally over distract or compress the frame and anatomy if both rings are fixed to the bone. 1 full revolution of the strut represents 2mm of compression/distraction travel.

Key components

Telescopic motor struts

Telescopic motor struts are used to drive angular motion around the frame's axis of rotation in a controlled, gradual fashion. The motors are designed with a threaded attachment post to outfit either a constrained or universal hinge coupling. Telescopic motors can be mounted in an anterior or posterior frame location as per the indication and surgeon preference.

- Quick release mechanisms are designed to allow for rapid telescopic length adjustment
- Clicking mechanism offers visual, audible, and tactile confirmation of an adjustment. Every "click" represents a 1/4mm of travel
- Dimple markers on clicking mechanism are designed to allow the patient to keep track of daily adjustments
- Easy to read adjustment scale
- Sizes (Including hinge coupling):
  - **Extra short: 142-167mm** (25mm of travel)
  - **Short: 161-195mm** (34mm of travel)
  - **Medium: 187-247mm** (90mm of travel)
  - **Long: 239-351mm** (112mm of travel)



Threaded post to attach universal or constrained hinge coupling

- Constrained hinge coupling — Lockable and designed to limit frame angulation to a single plane when range of motion control is desired
- Universal hinge coupling — Designed to permit angulation in multiple planes when additional construct range of motion is desired

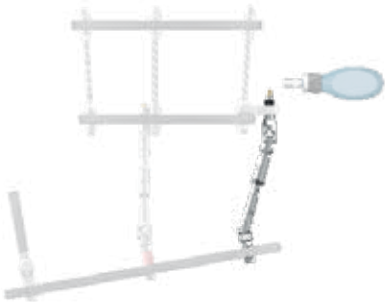
CAUTION

Flats on quick release mechanism are for finger adjustment only. Attempting to rotate with a wrench or pliers may damage the strut. To maintain intended performance, hinged telescopic struts and motors should not be re-sterilized beyond (100) autoclave cycles.

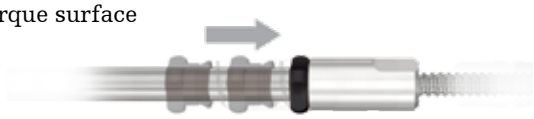
Universal hinge coupling

Constrained hinge coupling

Anteriorly mounted motor



Posteriorly mounted motor



Quick release safety nut

CAUTION

To avoid inadvertent disassembly of the quick release mechanism, do not loosen the colored safety nut beyond the etched line. If the colored safety nut is accidentally loosened beyond the etched line and the mechanism disassembles, simply push the colored safety nut and spring back into the quick release body and re-tighten the nut with clockwise turns until the assembly reengages.

Key components

Foot arches

- Fully assembled design for ease and speed of application
- Carbon fiber reinforced polymer offers strength and radiolucency
- Built-in hinged connection bolts allow for angular adjustment for additional construct versatility
- Available in 100, 120, 140, 155, 180 and 210mm diameters

NOTICE

Foot arches are attached to rings using the M8 connection nuts. To ensure easy application, assemble foot arches on rings prior to tensioning wires.

If the angle of the foot arch is changed after tensioning wires in the foot, wires may need to be re-tensioned.

⚠CAUTION

To maintain intended performance, carbon fiber rings and foot arches should not be re-sterilized beyond (50) autoclave cycles.

Key components

Rocker shoes

Independent shoe design allows for side-specific height adjustment when presented with an angled foot ring.

Anterior and posterior shoe ends feature a 15° slope to help facilitate normal gait.

NOTICE

M6 connection nuts are used to attach rocker shoes to foot rings. When additional clearance between the foot ring and rocker shoe is needed (i.e. to accommodate pin / wire fixation below the surface of the foot ring), use colored washers to create height offset.

CAUTION

Do not sandwich foot ring with (2) M6 nuts to attach rocker shoes. Use washers.

CAUTION

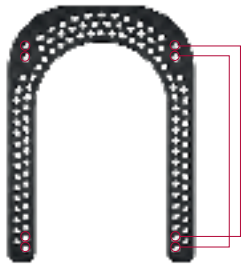
Rocker shoes are not offered sterile and must be applied post-operatively.

CAUTION

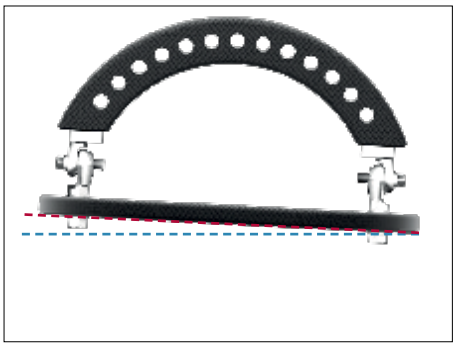
If rocker shoes are indicated, do not occupy dedicated mounting holes with other frame components. On open end of the foot ring, rocker shoes mount on inner row of holes.

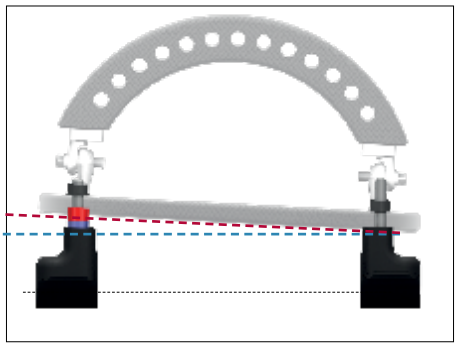
CAUTION

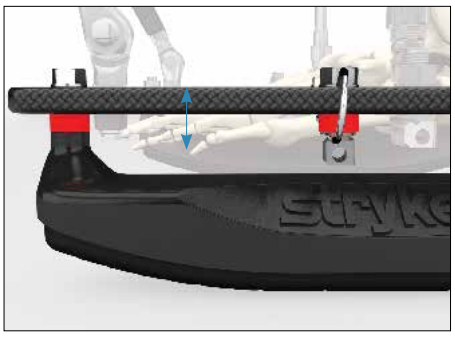
Encourage patients to use caution when walking on wet or slippery surfaces.



Rocker shoe mounting sites







Max clearance = 23mm
(incl. washer red 7mm)

Rocker shoe sizing

Left foot rings	Dia (mm)	Long rocker shoe size	
	100	Small rocker shoe long (4934-8-100)	
	120		
	140	Medium rocker shoe long (4934-8-140)	
	155		
	180	Large rocker shoe long (4934-8-180)	
	210		

Short foot rings	Dia (mm)	Short rocker shoe size	
	100	Small rocker shoe long (4934-7-100)	
	120		
	140	Medium rocker shoe long (4934-7-140)	
	155		
	180	Large rocker shoe long (4934-7-180)	
	210		

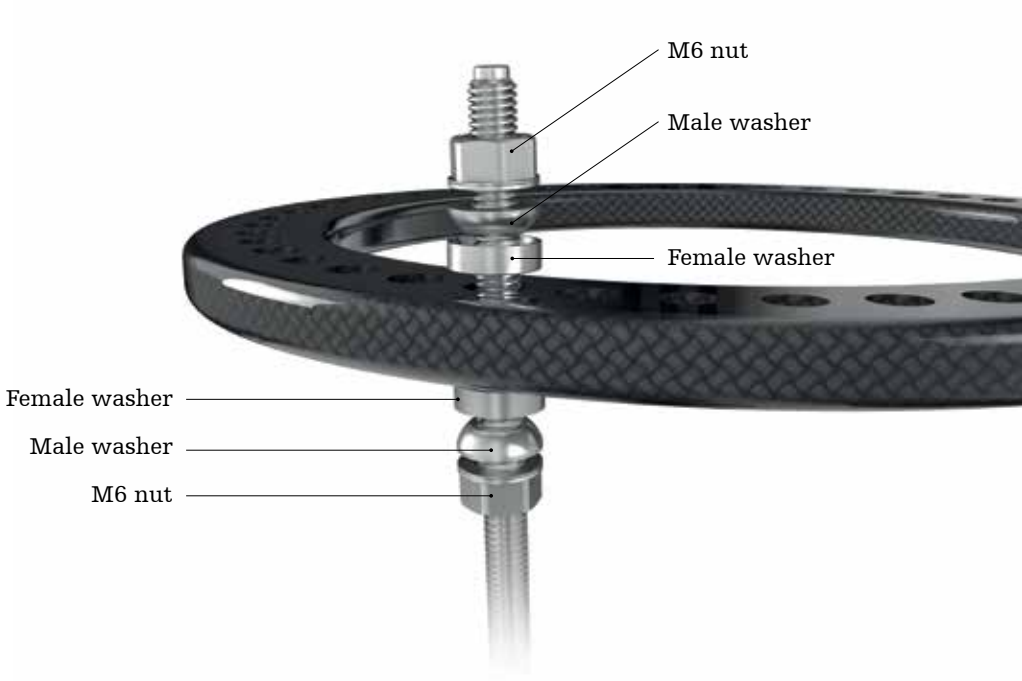
Key components

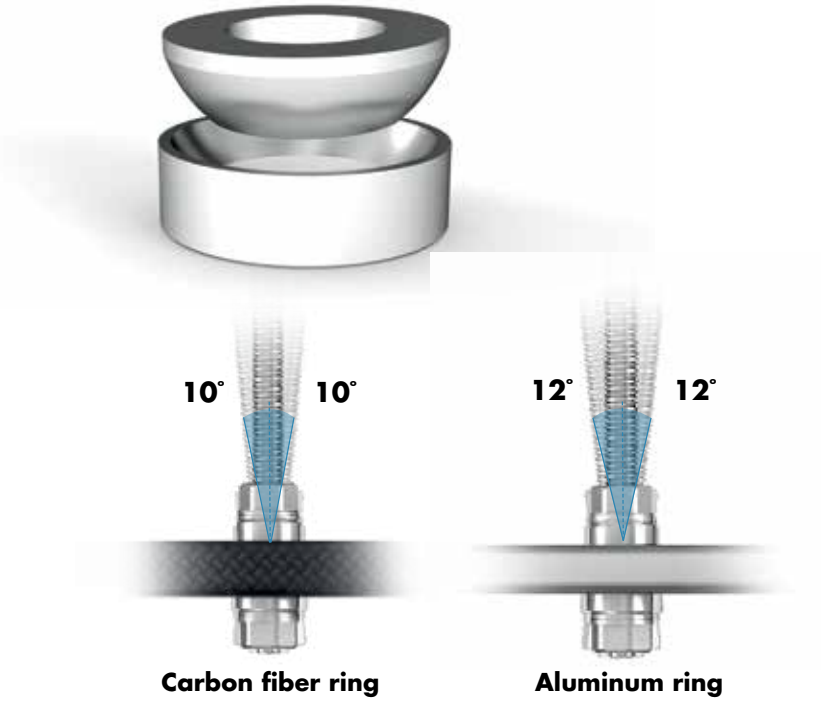
Spherical washer

Spherical washers are designed to allow angulation of the threaded rod components within the ring. This allows threaded rods to span to rings that are not parallel or of different diameters.The angulation is achieved by adding the conical / cup shaped washer assembly to both sides of the ring/threaded rod interface.

NOTICE

Spherical washers are attached using the M6 connecting nuts only. The female half of the washer is applied with the grooved surface to the ring. The male half of the washer is applied second, followed by the M6 nut.





Spherical washers can be used with both aluminum and carbon fiber rings. Rods can be angulated 12° from neutral when aluminum rings are used. Since the carbon rings are slightly thicker, 10° of rod angulation from neutral is possible.

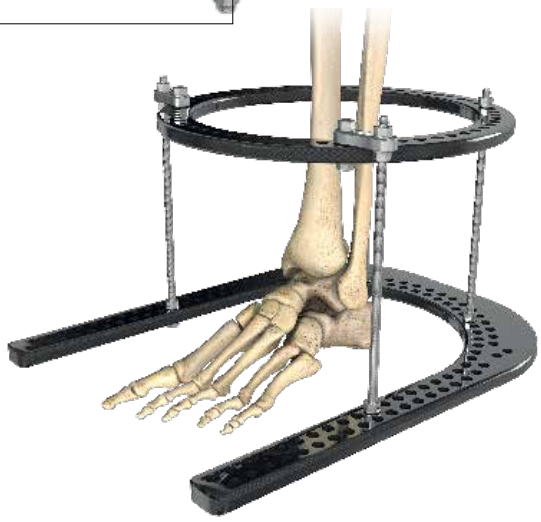
Key components

Slotted plates

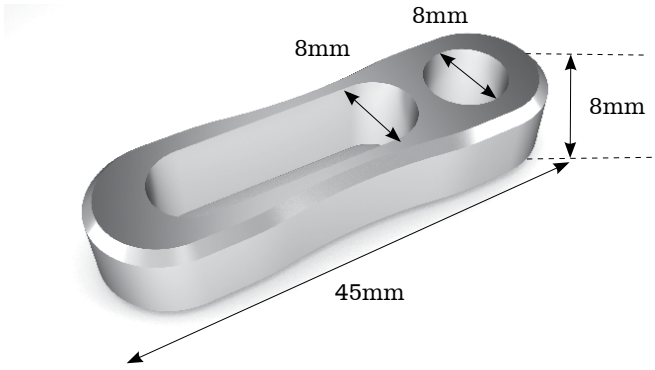
Slotted plates can be used to build a variety of offset component assemblies. Slotted plates are commonly used as modular ring "tabs" to capture threaded rods or struts that do not directly align with adjacent rings.

NOTICE

Slotted plates are connected to rings using medium M6 connection bolts and M6 nuts.



Slotted plates are designed to accommodate both 6mm and 8mm diameter components. In addition to offsetting 6mm threaded rods, slotted plates can be used to attach components such as telescopic struts and pin / wire fixation components.



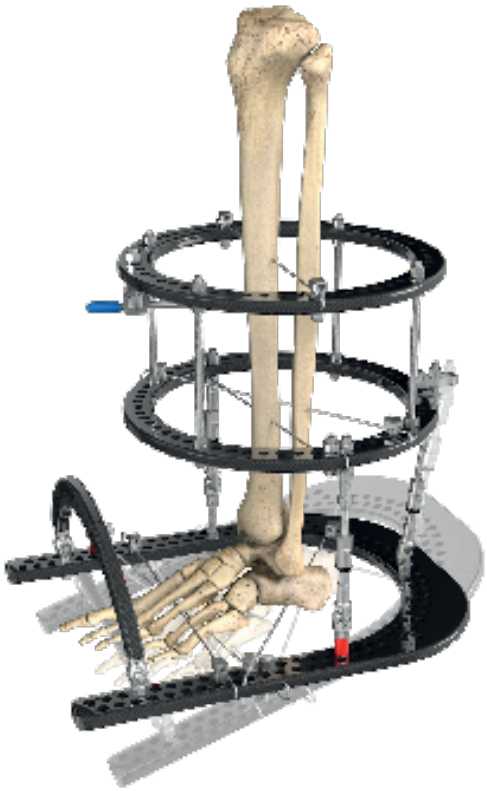
Operative technique

Operative technique: Equinus foot correction

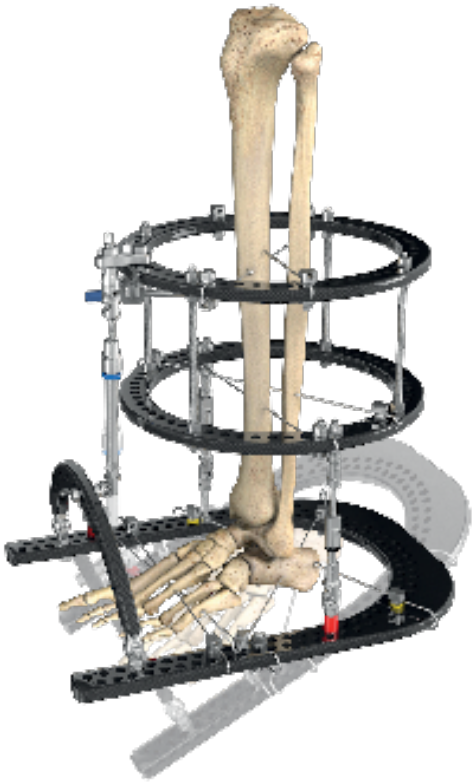
External fixation correction strategies

Several technique variations exist for equinus foot correction. All techniques require distraction of the ankle to protect the articular surface during correction. Gradual Correction techniques require a stable ankle at all times. It is important to note that pin and wire placement will vary by indication and surgeon preference. The steps below detail the recommended procedures for applying the Hoffmann LRF Gradual Correction components. The following construct example consists of a 2-ring tibial block, a foot ring, and a carbon fiber foot arch. It is recommended that the distal tibial ring has the same diameter as the foot ring.

Two (2) approaches for hinge placement are discussed: the ring block first approach and the guide wire first approach. Hinges are aligned along the joint line of the ankle (Inman's axis). Constructs with an anterior motor are referred to as "pull" constructs; constructs with a posterior motor are referred to as "push" constructs.



"Push" construct



"Pull" construct

⚠CAUTION

Due to the length limitations of the telescopic hinges, the Guide Wire First Approach may be advantageous in certain cases because placement of the hinges is not dictated by the distance of the ring block in relation to the ankle joint. Rather, the approximate location of the ring block is dictated by the length of the hinges. In either approach, it is important to leave at least 5-10mm of travel in the hinged telescopic struts to accomplish the final distraction. Do not mount the ring block at a distance that fully extends the length of the strut.

Operative technique: Equinus foot correction

Recommended tension levels

50kg Tension

- Wire bolt offset adapter, long (4933-1-005) used with wire bolt short (4933-1-001)

90kg Tension

- Wire bolt offset adapter, short (4933-1-005) used with wire bolt short (4933-1-001)
- Wires used on foot rings

130kg Tension

- Wire bolt, short (4933-1-001)
- Wire bolt, medium (4933-1-002)
- Wire bolt, long (4933-1-003)

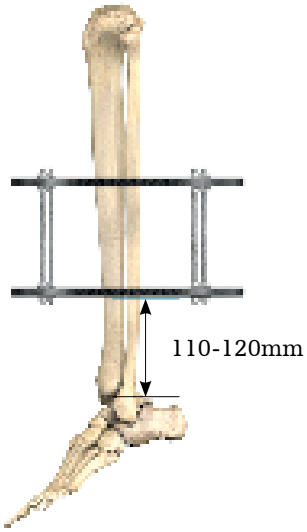
NOTICE

Utilize counter-torque instrumentation to minimize wire bending during final tightening.

Operative technique: Equinus foot correction

Method A – Tibial ring block first approach

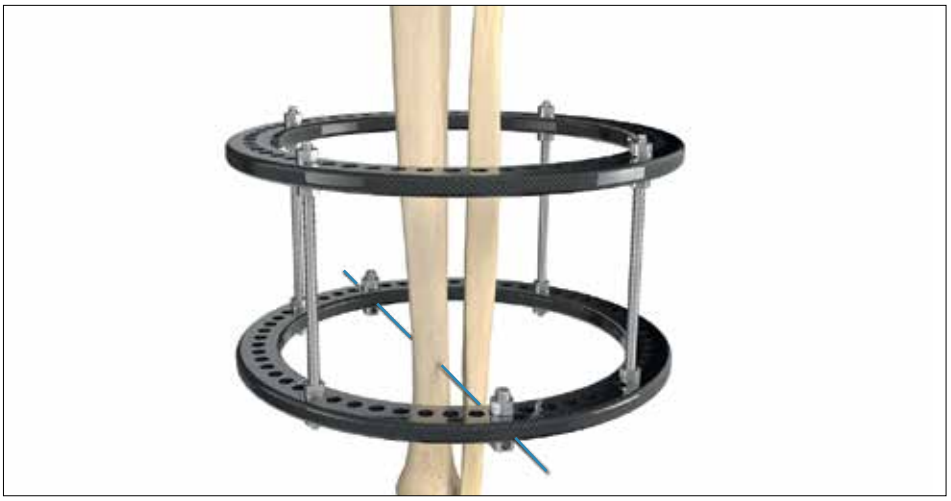
A1. Prebuild a 2-ring tibial block with 4 threaded rods or 60mm static struts. The lower tibial ring is placed 110-120mm above the level of the ankle joint.



A2. The 1st olive wire is an axial wire placed lateral to medial on the distal ring, 110-120mm above the level of the ankle joint. This wire will be placed on the bottom of the ring. There must be at least a 2-3cm of space between the ring and skin and the tibia is centered from medial to lateral.

A C-Arm is used to ensure that the olive is flush with the bone and the wire is tensioned.

The 2-ring construct can now be rotated around this wire to align the rings to the tibia (lateral view). The line of reference is the posterior cortex of the tibia.



A3. The 2nd olive wire is an axial wire placed medial to lateral at the level of the proximal ring. The wire is placed on the top surface of the proximal ring.

A C-Arm visualizes the olive flush with the bone and the wire is tensioned. These first two wires lock the 2-ring tibial construct.

The construct should now be assessed for position. The construct should be at right angles to the tibia (AP and Lateral View).

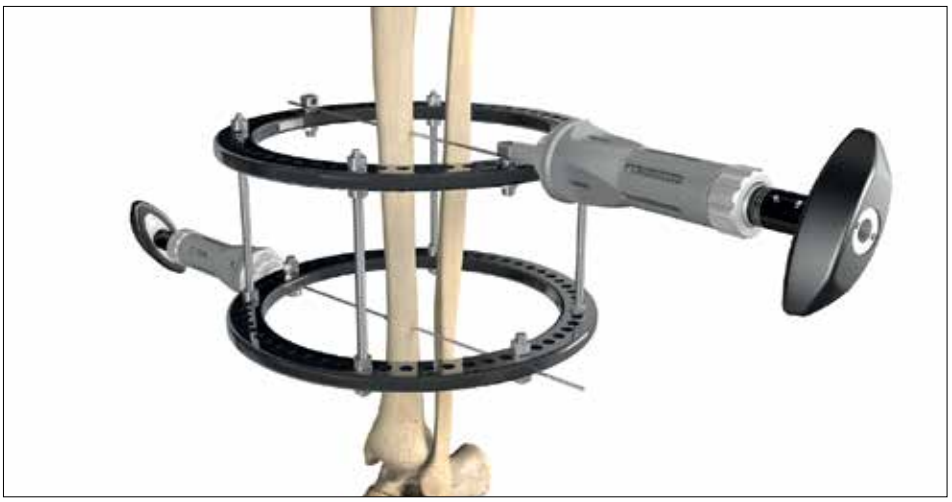
Operative technique: Equinus foot correction

Method A – Tibial ring block first approach

If the remaining connections are to be half-pins, the tension on the two wires is loosened and the wires are simultaneously re-tensioned. Alternately, two half-pins can be placed above and below each ring.

NOTICE

The following steps provide instruction on how to apply the frame using wires as the primary mode of fixation. In certain instances, half-pins may be preferred.



A4. The 3rd olive wire is a medial face wire placed on the bottom side of the proximal ring. This wire starts just lateral to the crest of the tibia and exits the tibia just in front of the posterior border on the medial side of the tibia. The first wire is de-tensioned and both wires are re-tensioned simultaneously.

A5. The 4th wire (smooth) is a fibular wire placed on the top of the distal ring from lateral to medial. This wire should exit through the fibula or just in front of the fibula. The first distal tibial ring wire is de-tensioned and both wires are re-tensioned simultaneously.

Operative technique: Equinus foot correction

Method A – Tibial ring block first approach

A6. The stability of the tibial construct is assessed and additional connections are added as necessary. As currently constructed, the tibial block is stable in medial-lateral bending but may be unstable in anterior-posterior bending. Since equinus is a sagittal plane deformity, the construct must be stable in that plane to prevent deformation of the rings. A-P stiffness is accomplished by placing an A-P Apex-pin on either side of the distal ring, proximal ring or both. The use of A-P half-pins will provide maximum rigidity in the sagittal plane.

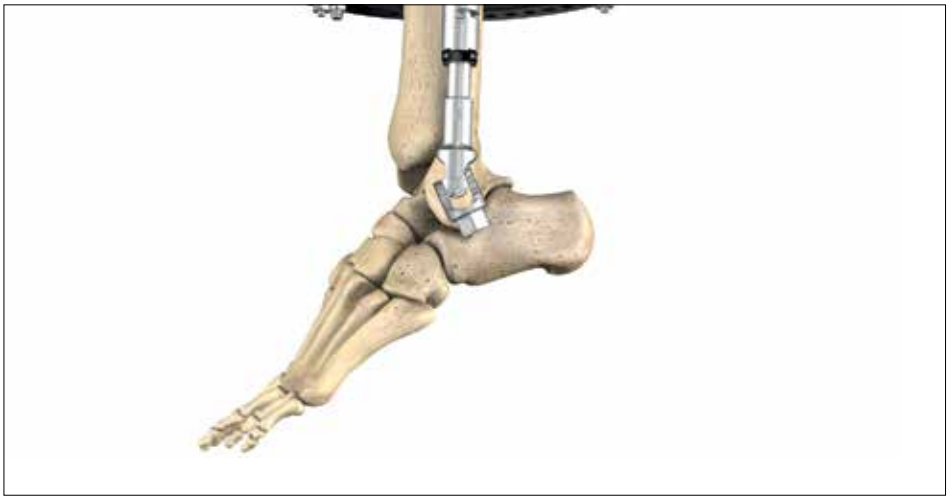
Hinge assembly

A7. Starting on the lateral side of the ankle, attach the ball-jointed end of the strut to the distal tibial ring.

If necessary, the ball joints can be unlocked to accommodate for non-orthogonal orientation of the tibial ring block. Once satisfactory strut trajectory is achieved, lock the ball joint to maintain intended positioning.Unlock the quick release mechanisms to grossly adjust the strut length so that the hinge aligns exactly with the tip of the lateral malleolus. A similar hinge assembly is attached to the medial side, with the medial hinge's pivot point aligned approximately 1cm distal to the tip of the medial malleolus. Once proper alignment is achieved, all hinges, ball joints, and quick release mechanisms are verified locked to maintain desired positioning.

⚠CAUTION

At full extension, hinged telescopic struts can span rings that are 150mm apart or closer (including 10mm needed for final distraction). If the distance between the foot ring and distal tibial ring exceeds 140mm, threaded rods with hinge couplings can be used as an alternative.



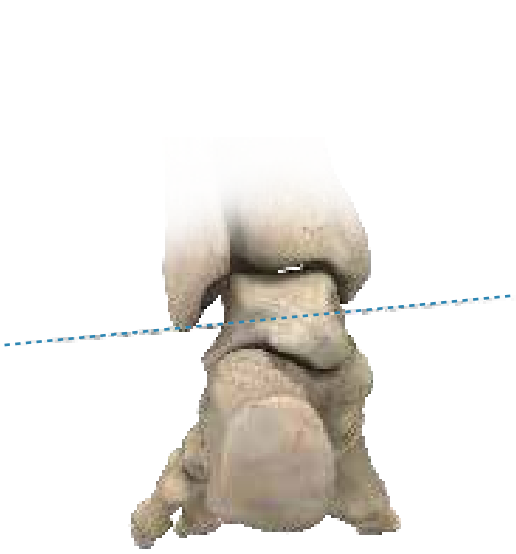
Continue with step AB1 on page 22.

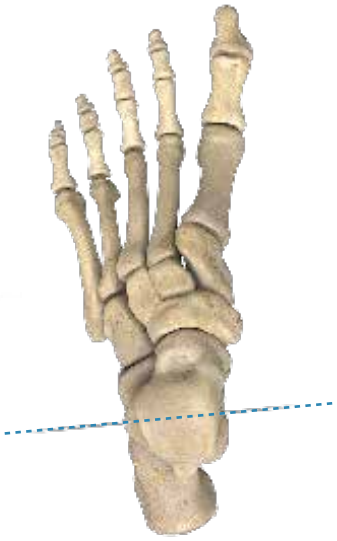
Operative technique: Equinus foot correction

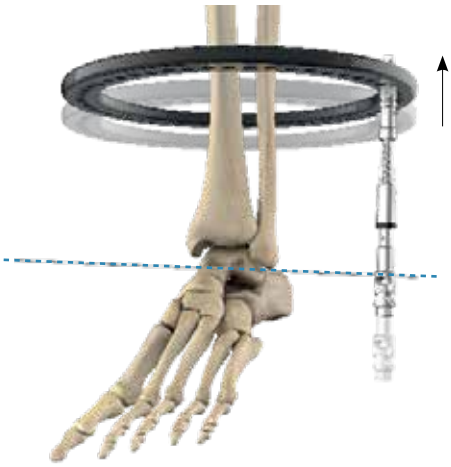
Method B – Guide wire first approach

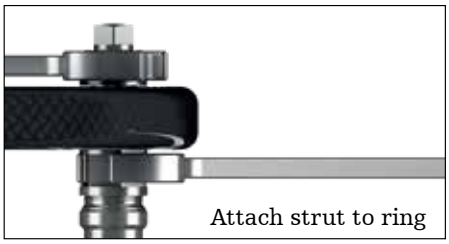
CAUTION

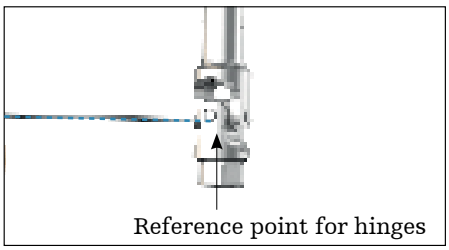
Due to the length limitations of the telescopic hinges, the Guide Wire First Approach may be advantageous in certain cases because placement of the hinges is not dictated by the distance of the ring block in relation to the ankle joint. Rather, the approximate location of the ring block is dictated by the length of the hinges. In either approach, it is important to leave at least 5-10mm of travel in the hinged telescopic struts to accomplish the final distraction. Do not mount the ring block at a distance that fully extends the length of the strut.











B1. A guide wire is used to define the axis of rotation of the ankle joint. If using a closed ring or ring block, slide rings onto leg first.

With fluoroscopic assistance, insert a smooth wire through the talus from approximately 1cm distal to the tip of the medial malleolus aiming toward the tip of the lateral malleolus.

The starting position is anterior / medial. Aim your wire in a slightely posterior / lateral direction.

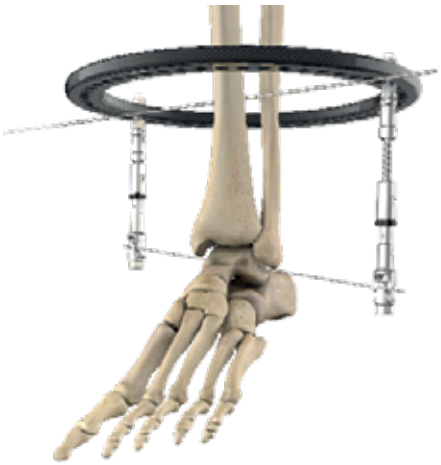
B2. Slide tibial ring or ring block onto the leg.

Using the guide wire as a reference point for the hinges, attach the ball-jointed end of the struts to the distal tibial ring. To avoid interference with the hinges, the targeting wire can be cut short on either side so that the tip of the wire aligns with the hinge's pivot point.

Once struts are attached, make side-specific adjustments to the length of each strut to accommodate non-orthogonal placement of the tibial ring/ring block if necessary. The total travel possible of the Strut is 25mm.

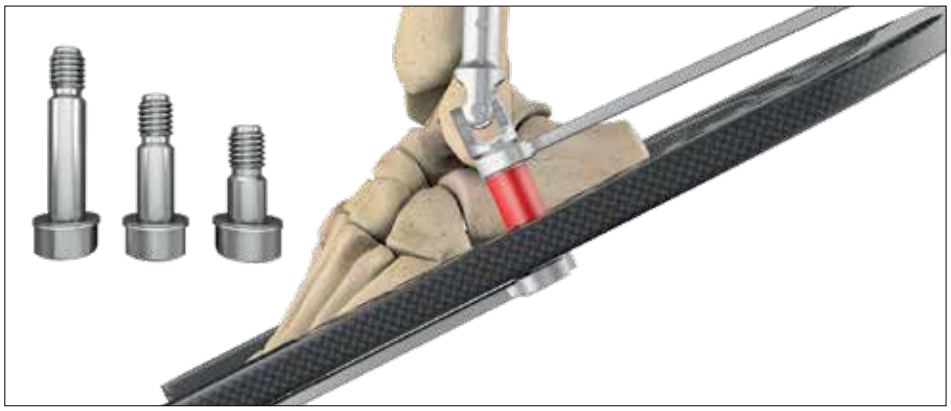
Before fixating the tibial ring / ring block, ensure that each strut is compressed with at least 10mm of length left to accomplish the final distraction.

B3. Insert the first olive wire as described in prior steps (see A2) and attach the ring / ring block with fixation of choice (e.g. see steps A3 – A6).



Operative technique: Equinus foot correction

AB1. The foot ring is attached to the hinged end of the strut using the M6 connection bolts. M6 Connection bolts come in 3 different lengths and can be used in conjunction with washers to accommodate height offset of the hinge in relation to the foot ring.

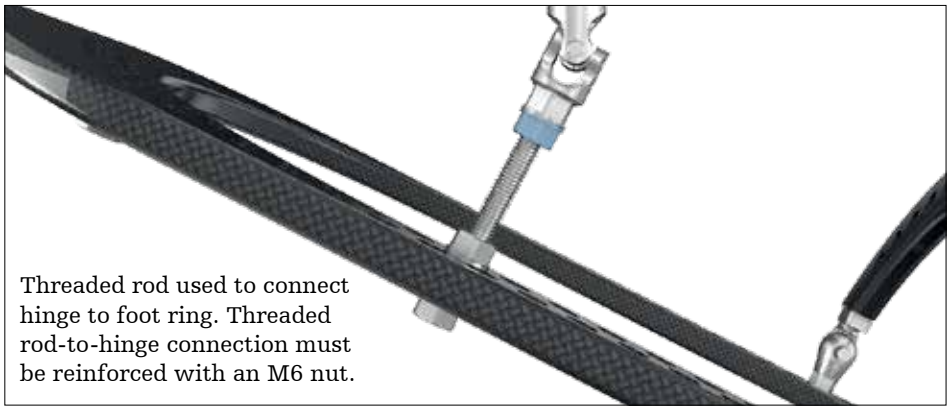


NOTICE

Utilize the hinge's counter-torque surfaces to prevent unwanted rotation of the hinge during final tightening of the connection bolts.

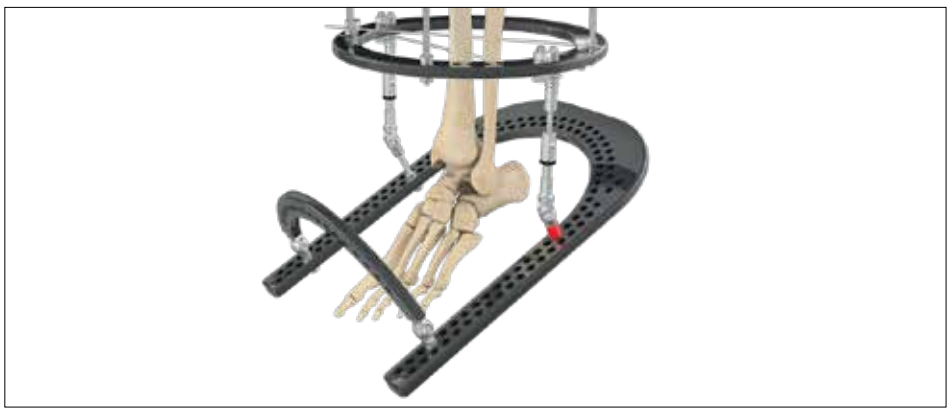
NOTICE

Make sure to check the hinges' range of motion by plantar and dorsiflexing the foot ring. Checking for smooth motion of the foot ring will verify that the hinges have not rotated during final tightening.

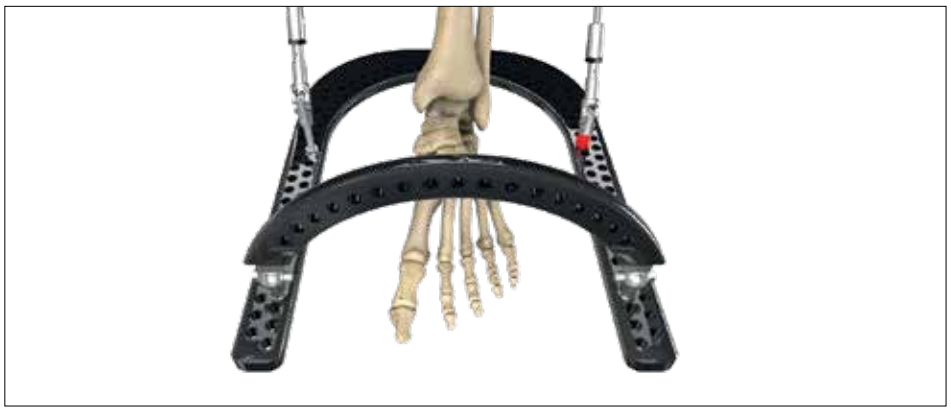


Threaded rod used to connect hinge to foot ring. Threaded rod-to-hinge connection must be reinforced with an M6 nut.

The long M6 connection bolt with washers can span a 16mm gap between the foot ring and the hinge attachment sites. If the distance between these connections exceeds this length, short threaded rods and M6 connection nuts can be used to connect the hinges to the foot ring.



A similar hinge assembly is attached to the medial side. Once proper alignment is achieved, all hinges, ball joints, and quick release mechanisms are verified locked to maintain desired positioning.



⚠CAUTION

Placing hinges too far posteriorly may result in the impingement of articular cartilage, even after distraction.

Operative technique: Equinus foot correction

Foot ring fixation

NOTICE

To ensure easy application, the foot arch should be securely mounted to the foot ring before wires are tensioned. Attaching the foot arch a few holes back from the open end of the foot ring may help maintain a more vertical orientation of an anteriorly place motor.

AB2. The 1st foot wire is an olive wire placed lateral to medial through the calcaneal tuberosity. This wire is placed on the top of the footplate and is tensioned. Care must be taken to avoid the neurovascular structures on the medial side of the calcaneus. In some cases, more of a direct lateral to medial wire trajectory may help keep the wire in the safe zone.

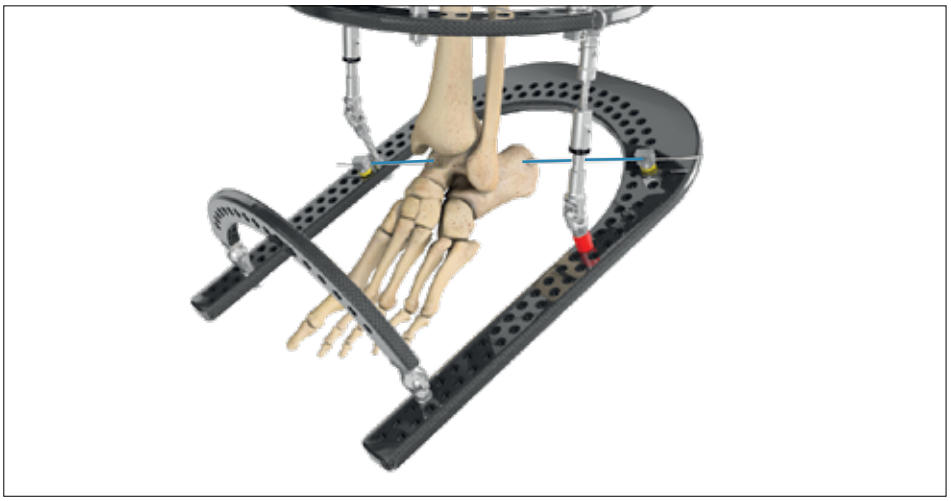
AB3. The 2nd foot wire is an olive wire placed medial to lateral at the level of the metatarsal bases.

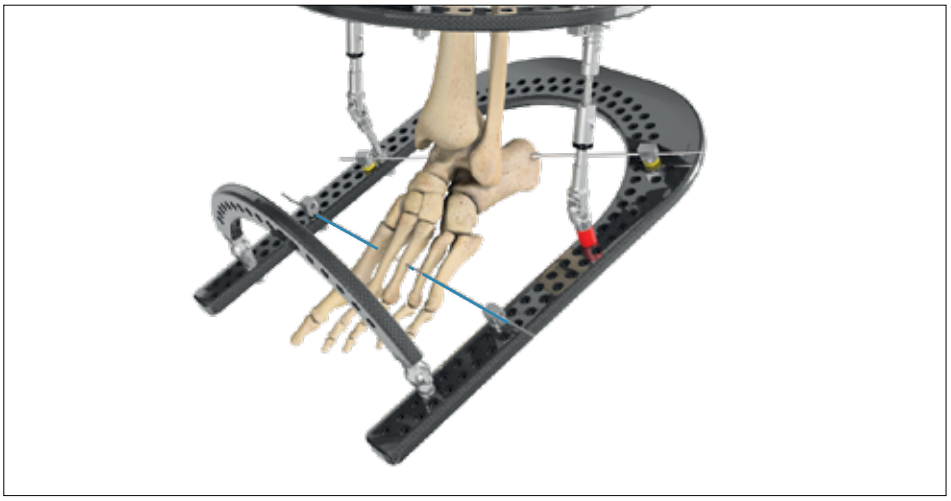
This wire may actually be placed more distal to increase the lever arm for equinus correction.

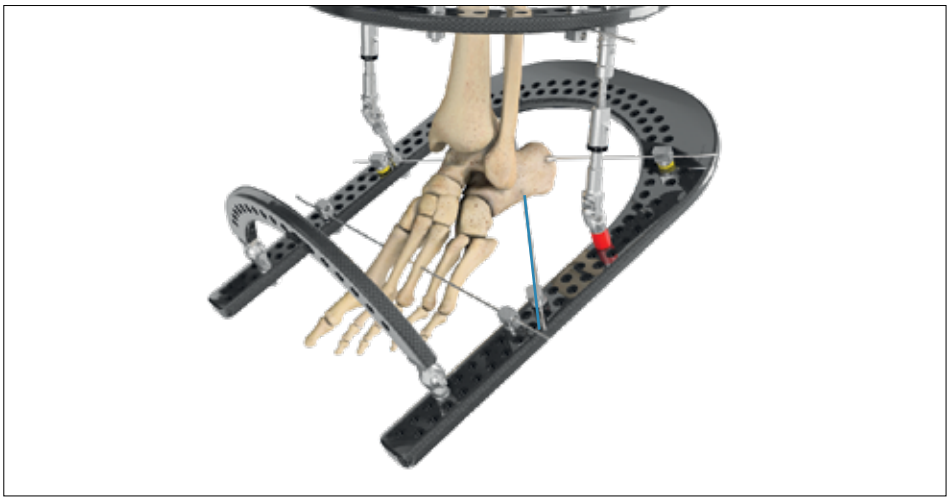
The wire is tensioned and the foot should now be centered in the footplate.

AB4. Minding the calcaneal safe zones, the 3rd foot wire is placed above the foot ring and enters the just in front of the achilles tendon. Wire is aimed from posterior /medial to anterior / lateral.

The first calcaneal wire is de-tensioned and both wires are re-tensioned simultaneously.



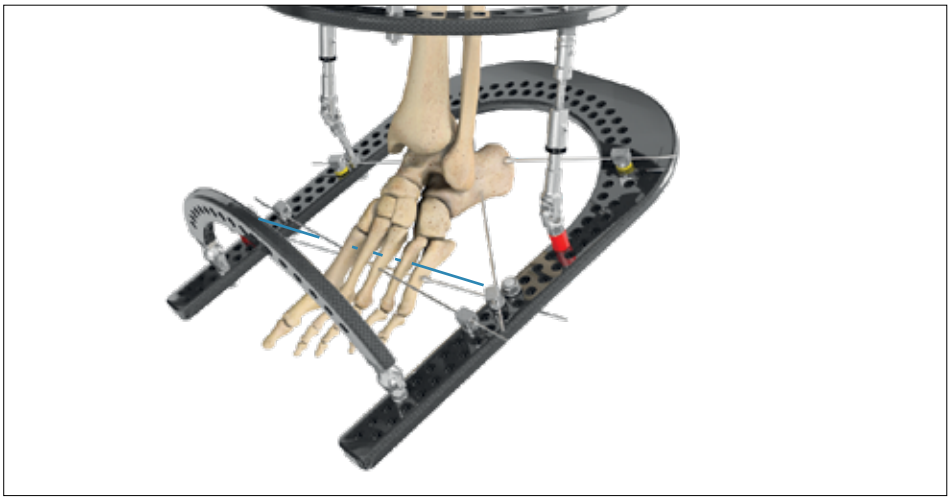




Operative technique: Equinus foot correction

AB5. The 4th foot wire is a lateral to medial olive wire at the level of the metatarsal bases. Placement above or below the footplate is dictated by local anatomy.

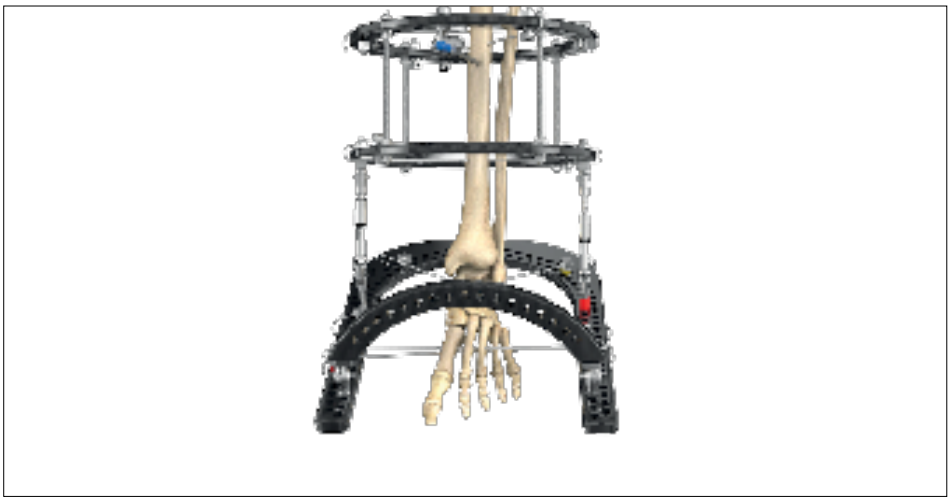
The first forefoot wire is de-tensioned and both wires are re-tensioned simultaneously.



AB6. With the hinges aligned and fixation in place, the construct is assessed to verify unobstructed dorsiflexion - plantarflexion.

NOTICE

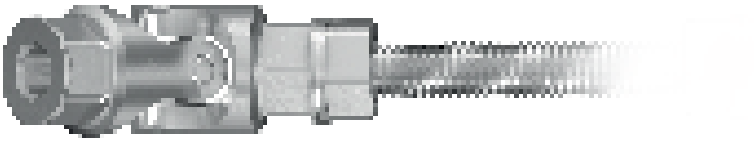
An additional wire may be placed in the talus to prevent distraction though the subtalar joint.



Alternative construct

Threaded rod assembly

A hinge attached to the end of a threaded rod can be used as a simple alternative to the hinged telescopic strut. Distraction can be accomplished by incrementally loosening and tightening the nuts below and above the tibial ring until the desired amount of distraction is achieved. Hinge placement methods and notes should be followed as outlined in previous sections of this guide.



Reinforce the universal hinge coupling with M6 nuts to help prevent connections from loosening throughout the course of treatment

⚠CAUTION

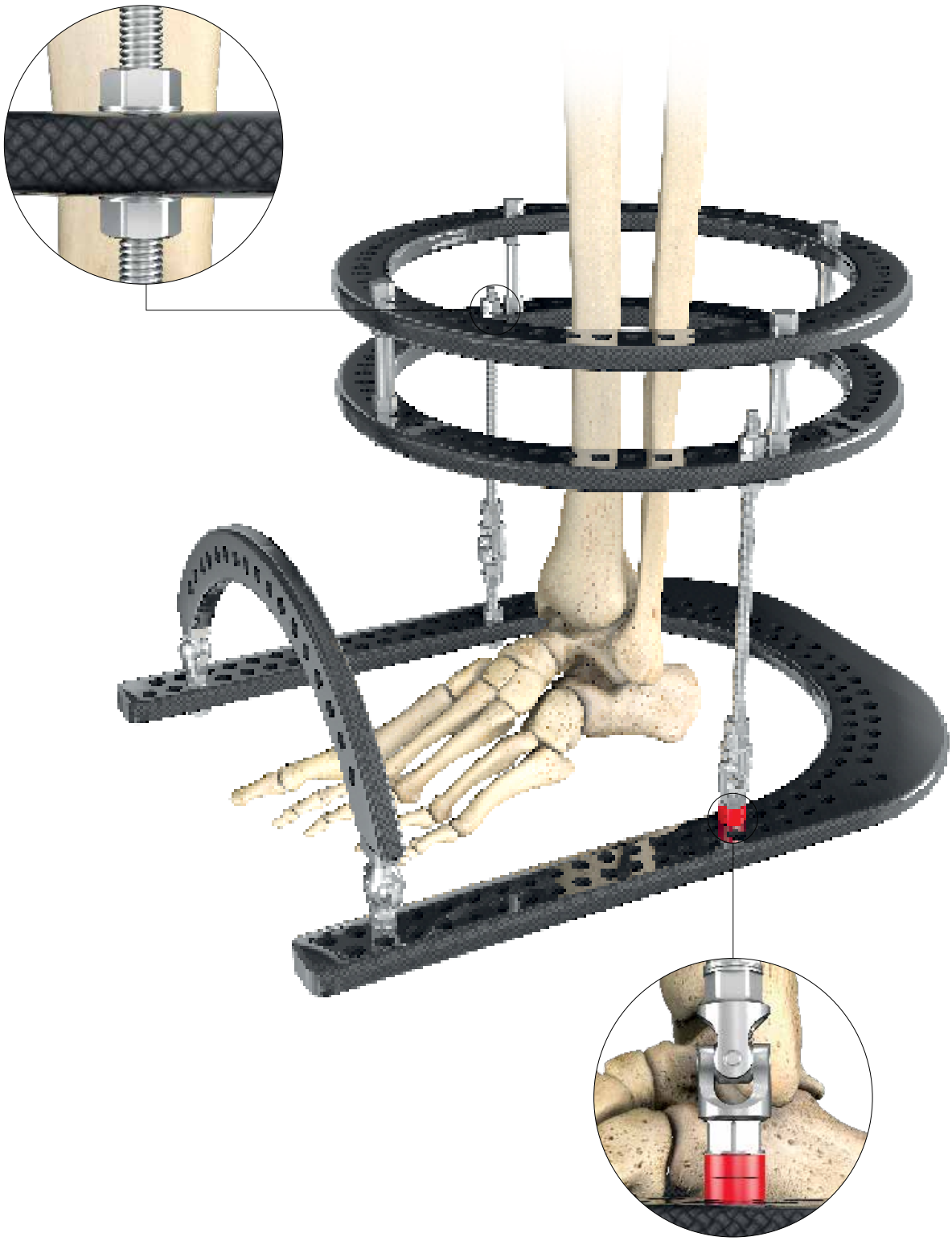
Make sure to select a long enough threaded rod to allow for 10mm of distraction.

NOTICE

One full revolution of the M6 nut equates to one millimeter of distraction.

Alternative construct

Threaded rod assembly



Operative technique: Equinus foot correction

Telescopic motor attachment

AB7. Telescopic motors can be applied posteriorly (push construct) or anteriorly (pull construct) based on the degree of angulation and surgeon preference. Once the mounting approach is confirmed, the distance between motor attachment sites is measured and the appropriate length motor is selected. Based on the indication, the universal or constrained hinge coupling is securely tightened to the end of the motor. As per surgeon discretion, the equinus should be over corrected by 10 degrees if indicated. This should be taken into account when selecting the length of the telescopic motor.

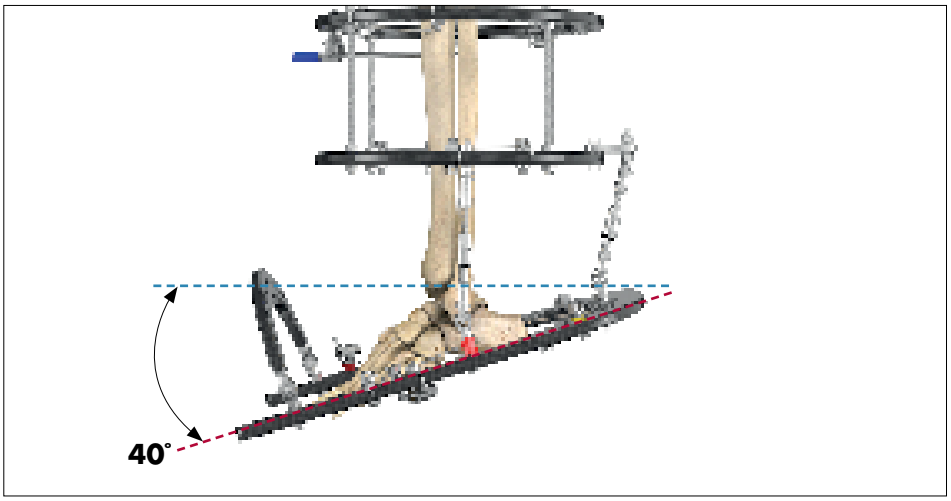
⚠CAUTION

The shortest length motor (extra short) is 142mm fully compressed (ring-to-ring distance). Equinus deformities with 40+ degrees of plantarflexion may be difficult to treat with a posterior motor since the posterior portions of the foot ring and distal tibial ring may be too close to mount the motor in between. Consider an anterior motor approach for this degree of deformity.

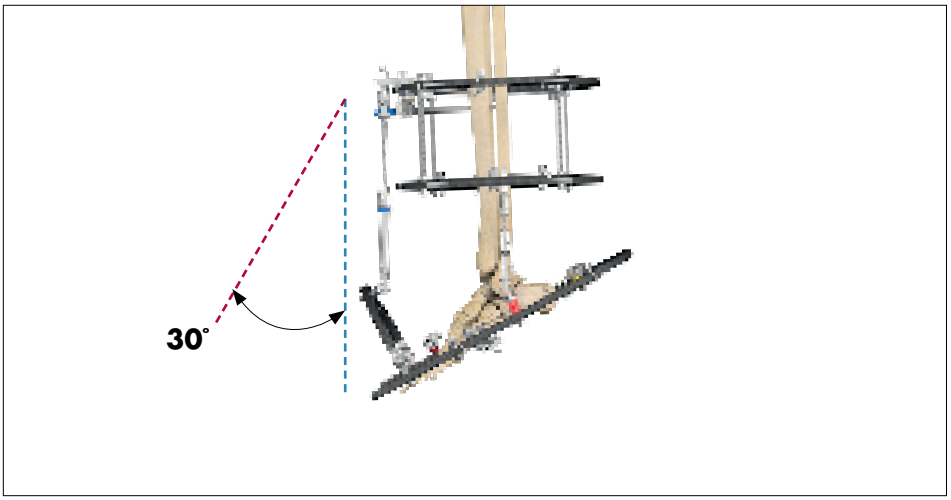
⚠CAUTION

When mounting an anterior motor, the angle of the motor should be 30º or less.

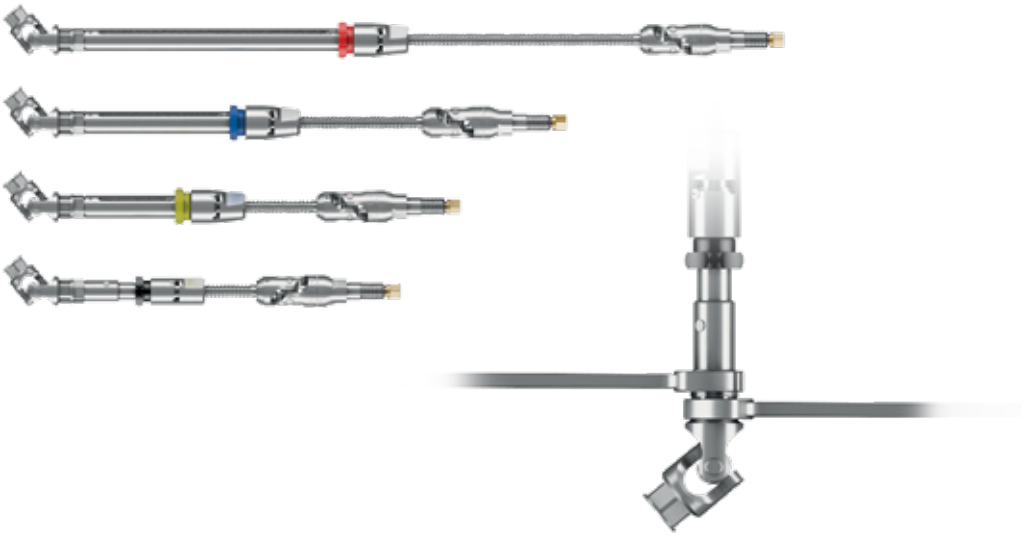
When taking the anterior motor mounting approach, the angle of the foot arch can be adjusted in preparation for the attachment of the motor. While the motor lengths overlap, selecting the longest size possible will minimize the need for motor change outs.



Posterior push construct



Anterior pull construct



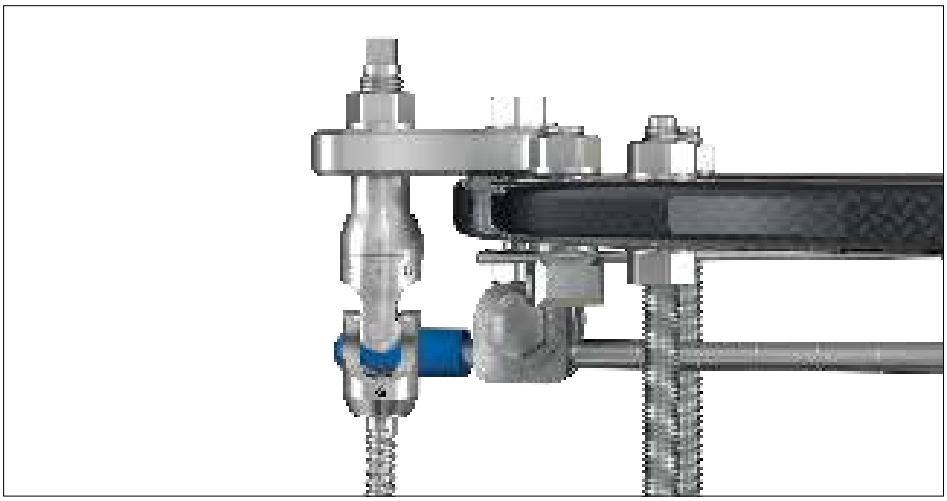
Operative technique: Equinus foot correction

NOTICE

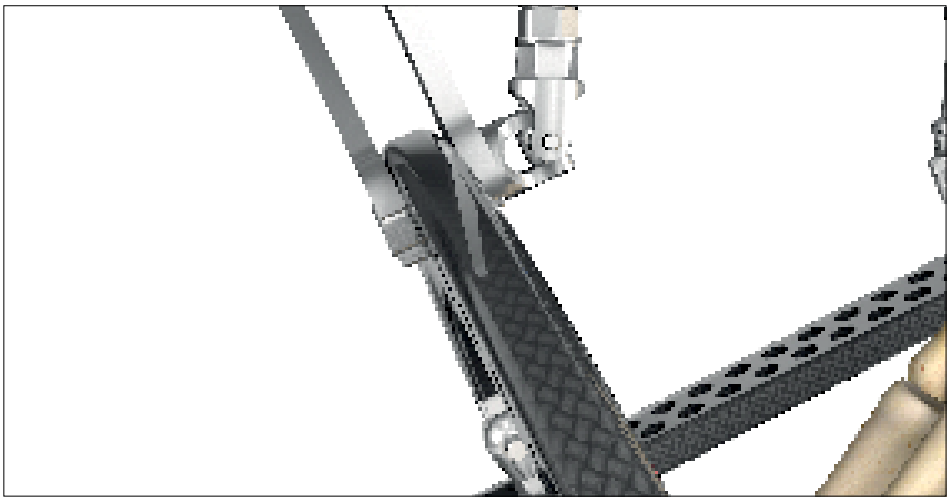
Attachment of the motor can be done before or after final distraction of the ankle.

Once the motor subassembly is assembled, the clicker end of the motor is attached to the ring using a short M8 connecting nut.

To offset the attachment of the motor on the tibial block, a slotted plate can be applied to the ring using a medium M6 connection bolt and nut.



On the hinged end, the M6 connecting bolts are used to attach the motor to the ring and / or foot arch. Utilize the motor's counter-torque surfaces to definitively secure each end.



⚠CAUTION

Before surgery is complete, confirm that access to the motor's adjustment point is not obstructed by other frame components.

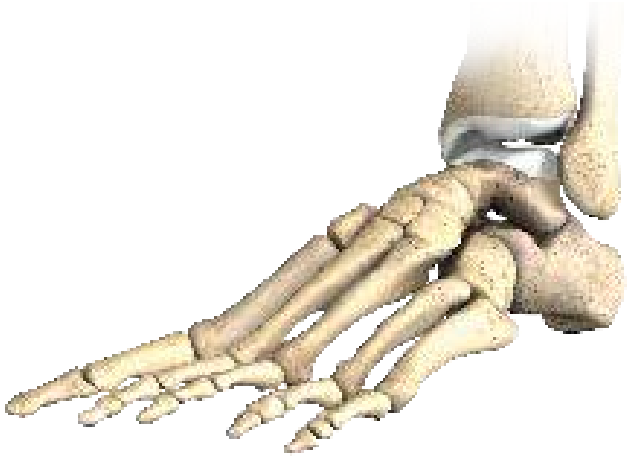
⚠CAUTION

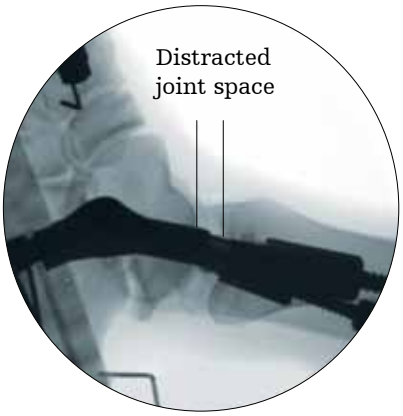
The dimple markers on the clicking mechanism's counting wheel should be aligned in the starting position: Single reference dimple on top portion of the counting wheel should align with the single dimple mark on the lower portion of the counting wheel. This is designed to allow the patient to keep track of quarter millimeter adjustments by starting them in the initial start position.

Operative technique: Equinus foot correction

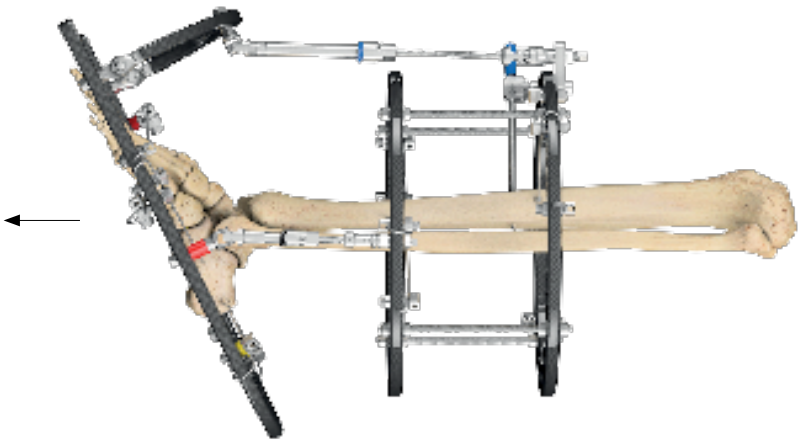
Final distraction

AB8. Distraction is necessary to protect the articular cartilage during equinus correction. The amount of distraction needed is based on the specific indications of the patient and surgeon discretion. The distraction is done intraoperatively on the OR table.





1. Distraction of the struts needs to be done progressively. For example, the quick release on the medial strut should remained locked while the quick release on the lateral strut is unlocked and manually distracted 2-3mm by pulling on the foot ring assembly. The lateral strut is locked to hold the initial distraction while the medial strut is adjusted 2-3mm. Repeat adjustments until the joint space is uniformly distracted to the appropriate distance.
2. Once the desired amount of distraction is achieved and confirmed, the quick release mechanisms are relocked to maintain the distraction
3. If needed, fine length adjustment features of the hinged telescopic strut can be used until the desired amount of distraction is achieved. When taking this approach, first confirm the quick release mechanisms are locked. Adjust each strut one at a time, keeping one strut fully locked while the other is being adjusted.



NOTICE

One full revolution of the strut equals 2mm of distraction.

⚠CAUTION

After distraction, confirm that hinges are aligned on the ankle joint's center axis of rotation and ensure that all component interfaces are definitively locked tight.

Operative technique: Equinus foot correction

Post operative adjustments

During the post-op gradual adjustment phase, the patient can utilize the manual adjustment instrument to actuate the motor and slowly dorsiflex the foot. The counting wheel on the adjustment instrument can be used to keep track of daily corrections.

⚠CAUTION

Fast adjustment rates may lead to complications including soft tissue / neurovascular damage. Rates of correction are indication-specific and may vary patient-to-patient.

Rates of correction may also differ when taking an anterior motor approach vs. a posterior motor approach.

Once the custom adjustment schedule is devised by the surgeon, the patient or caregiver can execute gradual corrective adjustments as prescribed. One full revolution of the clicking mechanism (8 1/4mm clicks) represents 2mm of motor compression / distraction. To compress the length of the motor (as performed with an anterior "pull" construct), the clicking mechanism is turned clockwise. To distract the motor (as performed with a posterior "push" construct), the clicking mechanism is turned counter-clockwise. Take caution not to rotate the clicking mechanism while applying the adjustment driver. Typically the 1mm of motor travel is broken up into (4) 1/4mm adjustments (4 clicks).

⚠CAUTION

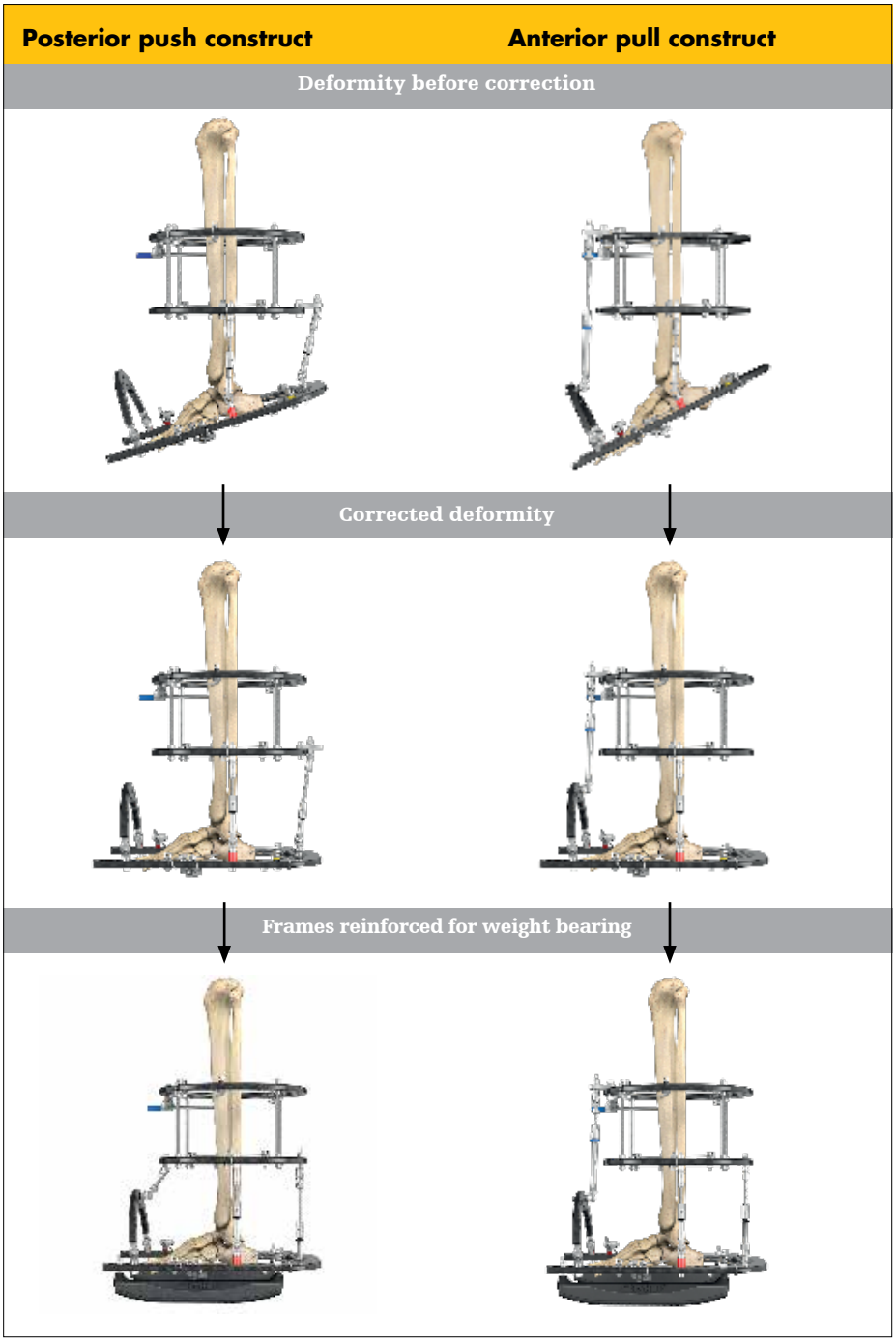
When making adjustments, use caution not to erroneously adjust the wrong frame components. Only make adjustments to the prescribed motor.

After a full day of adjustment (4 clicks = 1mm of motor travel), the correction should be verified by the following:

1) The reference dimple on the top of the clicker should be aligned with the single dimple marker on the lower half of the counting wheel. This represents a half revolution of the clicker (corresponding to 1mm of travel).

2) The reference markers found on the counting wheel of the adjustment driver should match the dimple reference markers on the motor's clicker. After a full day (4 clicks) the adjustment instrument should be adjusted to the single dimple marker.

3) Using the correction schedule as a reference, confirm that the motor's lengthening scale reads the appropriate number. For example, if the motor is being compressed and is at 305mm at the start of the day, after 4 clicks, the scale should read 304mm. This will also confirm that the adjustment is taking place in the proper direction.



Operative technique: Equinus foot correction

Reinforcing frames for weight bearing

Partial weight bearing with crutches or walker can begin during the last 10 degrees of correction. Full weight bearing can ensue when the deformity is fully corrected. At this point, the frame should be reinforced with additional support assemblies to accommodate an increased amount of loading.

⚠CAUTION

Once correction is achieved and patients are allowed to weight bear, an additional static telescopic strut or threaded rod assembly is strongly recommended for increased construct stability.

Anterior support assembly using hinges and threaded rods

Posterior support with universal telescopic strut

Operative technique: Equinus foot correction

Telescopic motor strut change out procedure

When executing a Gradual Correction procedure on a large angular deformity, there may be a need to change the frame's motor once all usable travel is consumed.

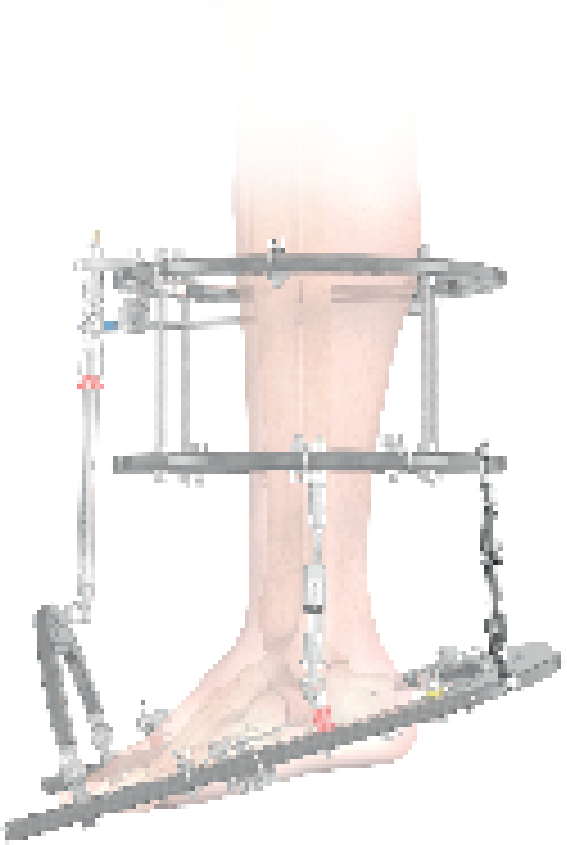
When exchanging struts, the surgeon must take care not to lose the correction that has already been achieved during prior days of correction.

Before removing a fully expended motor, the frame must be stabilized and reinforced to preserve the amount of correction already achieved. Several approaches exist for this procedure.

Supplemental Hoffmann components should be used to further stabilize the frame, especially if lockable hinges are not being used.

On the posterior portion of the frame, a universal telescopic strut can be used to span the rings proximal and distal to the joint space or osteotomy.

Be sure that the supplemental strut is securely tightened to the rings with the appropriate connecting nuts and also make ensure that all ball joints and quick release mechanisms are securely locked.



Posterior fixation with universal telescopic strut

Operative technique: Equinus foot correction

Telescopic motor strut change out procedure

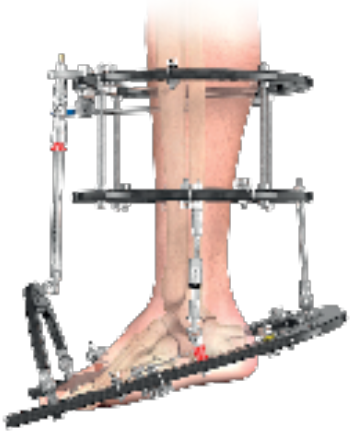
Alternatively, a simple hinge / threaded rod assembly can be built and used in a similar fashion. When taking this approach, confirm that the coupling is securely tightened to the ring and threaded rods using M6 connection nuts and bolts. Also confirm that the hinge coupling is locked.

Another available option is to utilize the Hoffmann 8mm posts and rods to span and stabilize the frame during a strut change out. Again, before exchanging the motor, ensure that all supplemental fixation components are securely locked.

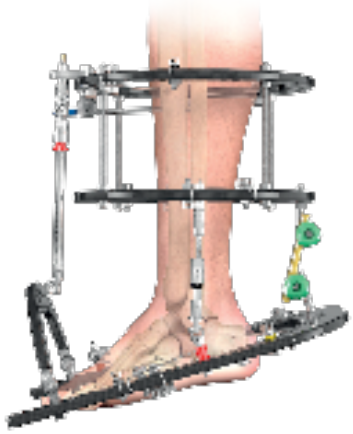
When assembling/applying the frame, select the longest strut possible to minimize the number of strut change outs.

During correction, the motor's travel will be used. Once the original motor is fully expended, the next size motor can replace it in a strut change out as described above.

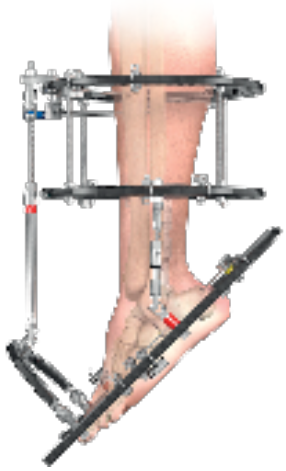
Supplemental fixation is applied to the frame during the change out, spanning the reference and moving rings. Confirm all connections and sub-assemblies are securely locked and stable.



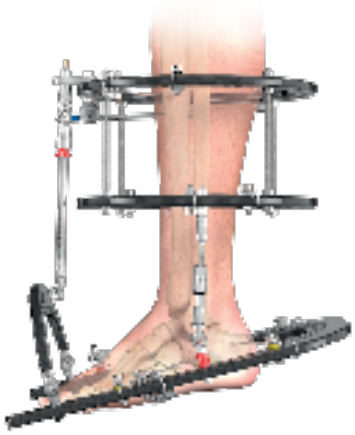
Posterior fixation with threaded rod



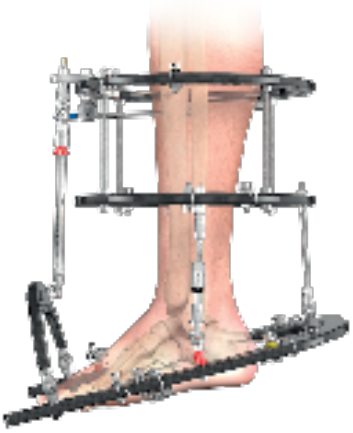
Posterior fixation with Hoffmann 3 components

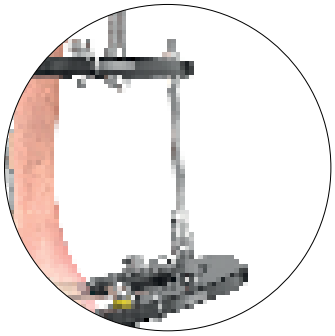


Anterior strut prior to correction



Anterior strut fully expended





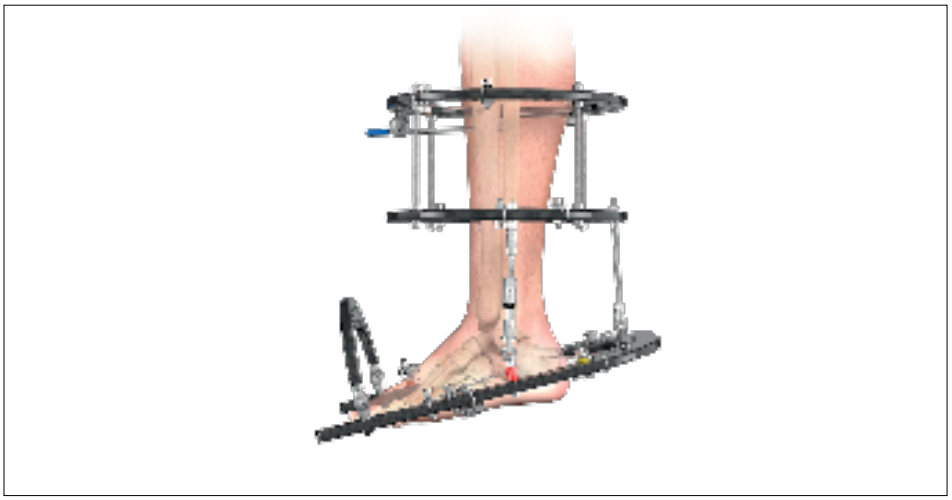
Operative technique: Equinus foot correction

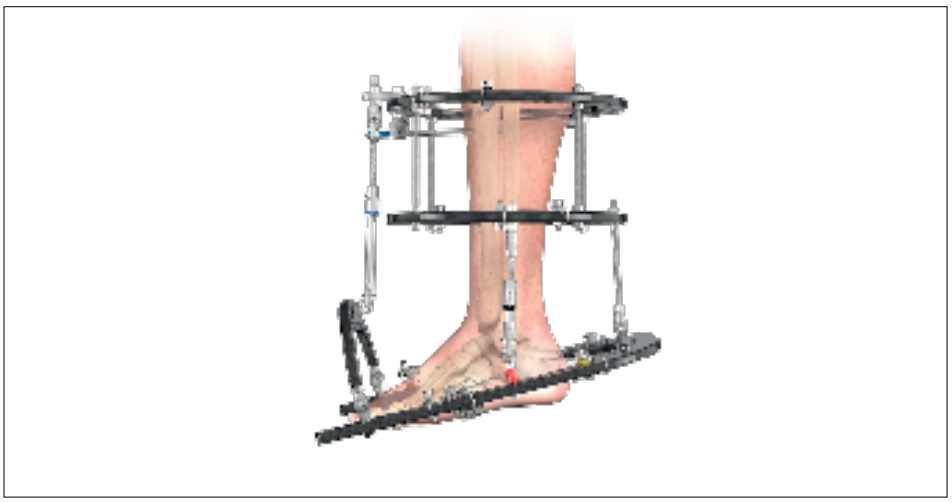
Telescopic motor strut change out procedure

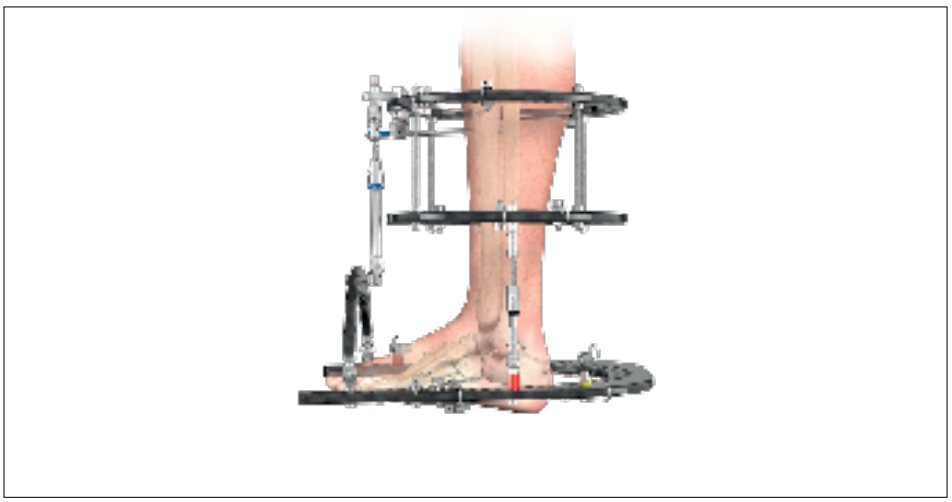
Once hinges are locked and the frame is securely reinforced, the original long telescopic motor is removed.

The medium telescopic motor is now attached in the fully extended position in place of the original long motor.

Once the new motor is installed, the supplement fixation is removed and correction can now continue until the deformity is fully corrected or until the next strut change out is required.







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Trauma & Extremities

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