GENERAL PRINCIPLES

TrueLok™

Ring Fixation System

General Principles: Limb Lengthening and Deformity Correction with TrueLok™ Ring Fixation System

ORTHOFIX®
ORTHOPEDICS

TrueLok™

Ring Fixation System

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INTRODUCTION

In 1951, Professor Gavril Ilizarov of Kurgan, Russia developed a new external fixation apparatus and technique to lengthen bones and correct bone deformities. The technique revolutionized the management of many previously unsolvable reconstructive problems.

In essence, the apparatus consists of circular rings and semi-circular external supports centered on the patient's limb and secured to the bone by crossed, tensioned wires and half pins. The rings are connected externally to provide stable bone fixation. The main external connecting elements are threaded rods, linear distractors, or hinges and angular distractors that allow the surgeon to adjust the position of rings relative to each other. The ring positions are manipulated either acutely or gradually in minute increments to perform the correction of the deformity, limb lengthening, or bone segment transportation as required by the surgeon.

The Ilizarov System experienced many modifications over the last fifty years. The TrueLok™ External Fixation System (TrueLok hereinafter), developed at Texas Scottish Rite Hospital for Children (TSRHC) in Dallas, Texas, is one of the modern variants of the original fixator, but preserves many of the original principles of Professor Ilizarov.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please kindly refer to the product IFU PQTLK, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

TRUELOK EXTERNAL SUPPORTS

TrueLok external supports are made from high-strength, anodized aluminum. They are offered in a variety of shapes and sizes to allow customizable frame constructs based upon particular clinical conditions, but have similar design features. All full rings, half rings, 5/8 rings, foot plates and double row foot plates have quadrant markings to simplify frame assembly. All external supports accept 6mm threaded components.

Full Rings
TrueLok full rings are the basic building blocks of the system. They are offered in 12 different sizes of internal diameters ranging from 80mm to 240mm **(Fig. 1)**. They have two sets of quadrant markings: anterior/posterior is a double line, medial/lateral is a single line.

Fig. 1

Half Rings
Half rings also come in twelve different sizes, ranging from 80mm to 240mm **(Fig. 2)**. The unique connection hole is a pocketed fit for positive location and stability. This pocketed fit provides a secure junction without losing fixation holes on either side of the connection hole. Half rings can be used alone, joined together to form a full ring, or connected to other external supports (i.e. foot plate extensions) depending on local anatomical requirements. There is one set of quadrant markings: a single line, which matches the medial/lateral markings on full rings of the same diameter.

Fig. 2

5/8 Rings
5/8 rings are offered in 9 sizes, ranging from 100mm to 200mm **(Fig. 3).** These partial rings can be useful at the joints to extend the range of motion possible while in the fixator. 5/8 rings have two sets of quadrant markings, matching the markings found on full rings of the same diameter.

Arches
Arches are manufactured in two sizes, a 90mm radius arch with holes covering a 95° span and 120mm radius arch with holes covering an 85° span **(Fig. 4).** Arches are commonly used to secure half pins in the proximal femur and proximal humerus.

Foot Plates
A foot plate is a modified half ring with elongated ends. They are available in nine sizes, ranging from 100mm to 200mm **(Fig. 5).** The pocketed fit connection holes at the ends of the foot plate can be used to connect foot plate extensions, or another foot plate, to create a customized foot support assembly for any shape and size of foot. The foot plate has two sets of quadrant markings, matching the markings found on full rings of the same diameter.

Foot Plate Extensions
Foot plate extensions are offered in two lengths: three hole and five hole **(Fig. 6).** One end has a pocketed fit connection hole, while the opposite end is tapped to accept a standard 6mm threaded element. A pair of foot plate extensions, used in conjunction with a foot plate and half ring, provide the ability to build a custom, three dimensional foot support assembly to accommodate virtually any shape and size of foot.

Double Row Foot Plate
The double row foot plate is an enhanced version of the standard foot plate **(Fig. 7a).** The enhancements include a wider base, a second row of fixation holes, and a longer side mounting area for additional elements. The wider and longer fixation mounting area provides greater versatility for wire fixation and connection element attachment. The ends are tapped to accept a standard 6mm threaded element. The double row foot plate has two sets of quadrant markings, matching the markings found on full rings of the same diameter. It is available in three sizes, ranging from 150mm to 200mm.

Full Double Row Footplate
The full double row footplates **(Fig. 7b)** are also available in 160mm and 180mm from the TL-HEX™ range. This gives a further option of a complete oval footplate when necessary.

TrueLok RockerRail (56-24000)
The TrueLok RockerRail **(Fig. 8)** is compatible with foot plates from the TrueLok and TL-HEX TrueLok Hexapod System™. It is made of two rails with the underneath surface covered by special rubber to prevent patients from slipping. The two rails are adjustable to different heights depending on the foot plate position. For important medical information and maintenance, consult Instructions for Use PQ TLR, PQ TLK.

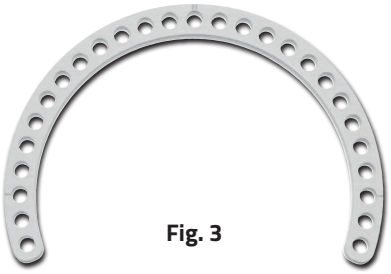
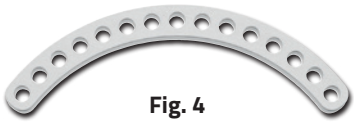


Fig. 3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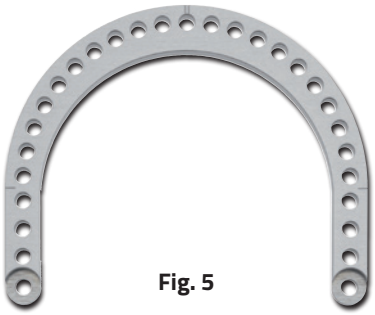


Fig. 5


Fig. 6

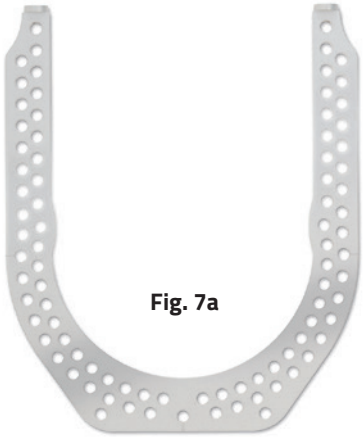


Fig. 7a

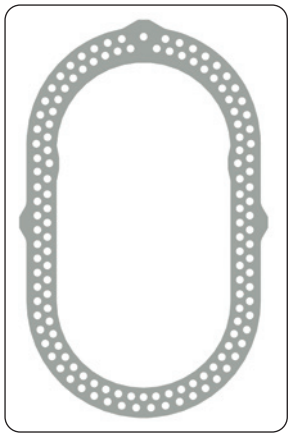


Fig. 7b

Fig. 8

TRUELOK ASSEMBLY ELEMENTS

All TrueLok assembly elements are made from stainless steel. Threaded elements have a standard M6 thread, and can be adjusted using a 10mm wrench.

Bolts
TrueLok bolts are offered in three lengths: 12mm, 16mm and 20mm **(Fig.9)**.

Fig. 9

Nuts
The TrueLok set offers two types of nuts. The standard nut is the primary assembly element used **(Fig. 10A)**, but the extended nut is useful for tightening elements placed in adjacent holes **(Fig. 10B)**.

Fig. 10A

Fig. 10B

Spacing Washer
Washers contained in the TrueLok set are 2mm thick **(Fig. 11)**.

Fig. 11

TRUELOK WIRES, HALF PINS, AND FIXATION ELEMENTS

General Principles of Segmental Fixation
The fundamental mechanical principle of the TrueLok system is to achieve stable transcutaneous segmental fixation of bone to permit stabilization or manipulation of those segments as required for the condition under treatment.

The basic fixation "unit" for a bone segment, as originally described by Ilizarov, is one ring with two crossed, tensioned wires. The ring should be perpendicular to the long axis of the bone segment, and ideally the limb is centered within the ring.

TL-HEX™ System is compatible with Standard bone screws, Titanium bone screws, Standard coated bone screws, Self-drilling coated bone screws, self-drilling bone screws, Transfixing Pins and Implantable wires.

Fig. 12

Fig. 13

Wires
1.8mm diameter TrueLok wires are available in two types: smooth **(Fig. 12)** and beaded (or stopper) wires **(Fig. 13).** Beaded wires provide a stop at the bone interface. Beaded wires serve two main purposes:
1. To enhance stability of fixation by preventing undesirable motion (i.e. bone translation when the wires are placed at a narrow crossing angle)
2. To move a bone segment in a desired direction (i.e. fracture reduction or segment compression)

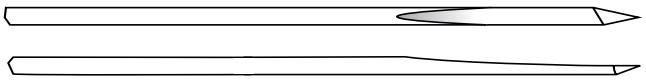


Fig. 14

Both wire styles have a bayonet-shaped, eccentric tip that efficiently drills through both cortical and cancellous bone without generating excessive heat **(Fig. 14).**
1.5mm diameter wires are also available - please see page 14.

Half Pins
TrueLok half pins are offered in 4, 5, and 6mm diameters, each having a total length of 180mm **(Fig. 15).** They are self-drilling, self-tapping.

Fig. 15

XCaliber™ Screws
XCaliber Screws can also be used with the TrueLok system. They are conical (6mm shaft, thread diameter 6-5.6mm), total length 150 or 260mm, thread length range: 30-90mm (step 10mm) **(Fig. 16)**. Also available sterile and with Hydroxyapatite coating.

Fig. 16

**Ask Customer Service for availability in your country.*

Universal Wire Fixation Bolt
The TrueLok universal wire fixation bolt **(Fig. 17a)** functions as either a slotted wire fixation bolt or a cannulated wire fixation bolt. The 10mm bolt head is slotted and the bolt neck is cannulated to accept a 1.8mm or 1.5mm wire. An additional design feature is the horizontal grooves on the slot and base of the head, which enhance the gripping force on the wire.

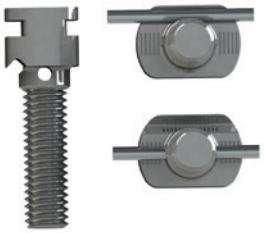


Fig. 17a

Wire Fixation Universal Low Profile
The low profile feature can be useful in specific applications when two rings are close and there is not enough space for the standard universal bolt or when two wires bolts are placed in two adjacent holes. The thinner profile helps in gaining space for inserting the tensioner tip (code 20116735 or 20116736) and better tension the wires. **(Fig. 17b)**

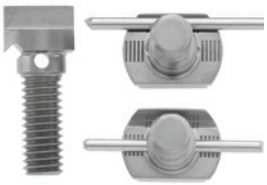


Fig. 17b

Slotted Washer
The TrueLok slotted washer is an oblique, hardened steel washer with a serrated slot to accept a 1.8mm wire. This washer may be seated over any threaded component to convert it to a slotted fixation device **(Fig. 18)** and used to capture the wire in positions when a wire fixation bolt cannot be used. The serrated slot is designed to increase the gripping force of this fixation element.

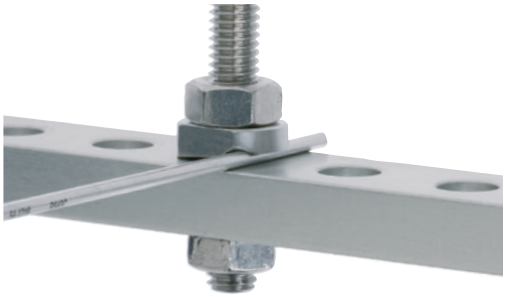


Fig. 18

Universal Half Pin Fixation Bolt
The TrueLok universal half pin fixation bolt **(Fig. 19)** has a sliding collar fitted over a teardrop shaped opening that provides secure fixation for 4, 5, and 6mm diameter half pins. The sliding collar has a serrated base and scalloped top to enhance the gripping force on the half pin and external support.

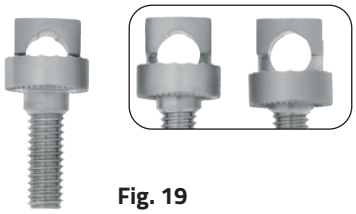


Fig. 19

TrueLok 8mm Half Pin Fixation Bolt
The TrueLok 8mm half pin fixation bolt **(Fig. 20)** is an enhanced version of the TrueLok universal half pin fixation bolt. It provides secure fixation for half pins with 5 and 6mm shank diameter. The 8mm half pin fixation bolt has a turnable collar that allows the insertion of a soft tissue protector. The specific design of the bolt minimizes the tension on the pins during tightening.

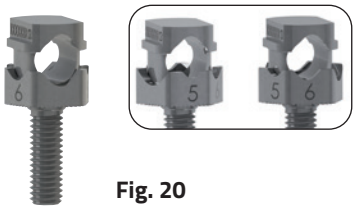


Fig. 20

8mm Bolt Wrench
The TrueLok 8mm bolt wrench **(Fig. 20a)** is provided to aid adjustment of the collar of the 8mm half pin fixation bolt between using a soft-tissue protector, 5 or 6mm half pin. The wrench is particularly useful when space is tight between fixation elements.

Fig. 20a

Posts
TrueLok posts **(Fig. 21)** are available in five sizes, ranging from 1 hole to 5 holes. They have a 10mm by 13mm cross section, allowing the surgeon to stabilize them with a 10mm wrench. The posts have a standard female threaded base, allowing them to be secured to an external support by a 12mm bolt. The serrations on the base prevent undesirable rotation after tightening.

Fig. 21

BASIC PRINCIPLES OF WIRE INSERTION, TENSIONING AND FIXATION

Wire Insertion
Insertion of an individual wire involves the following steps:

1. The wire is placed on the surface of the ring and pushed through the skin at the desired level and orientation to the bone surface **(Fig. 22).** Many considerations come into play when determining this orientation, including cross-sectional anatomy, location of the second wire, and the long axis of the bone segment. The wire should be passed straight through the skin along the desired axis of the wire. Fluoroscopy may be used to confirm proper orientation of the ring and the wire to the limb. The appropriate size ring, centered on the limb, or an entire pre-constructed frame may serve as a guide to proper orientation.

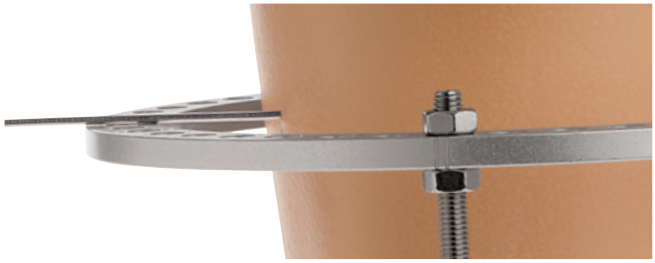


Fig. 22

2. Insert the wire through the bone using a slow drilling speed. Keep the wire straight by avoiding excessive pressure. Efforts should be made to keep the wire cool during insertion such as interrupted incremental advancement, using gauze soaked in saline to stabilize the wire, or setting a saline drip on the wire itself.

Fig. 23

3. Once the wire exits the bone, drill or tap with a hammer to the opposite skin edge. The skin on the opposite side of the limb should be stabilized over the wire prior to the wire exiting the skin.

4. Once the wire has exited, check the skin to see that there is no tension around the wire. If tension is present, withdraw the wire beneath the skin surface and then re-advance. Once satisfied, continue to advance the wire several centimeters beyond the ring to allow fixation and tensioning **(Fig. 23).**

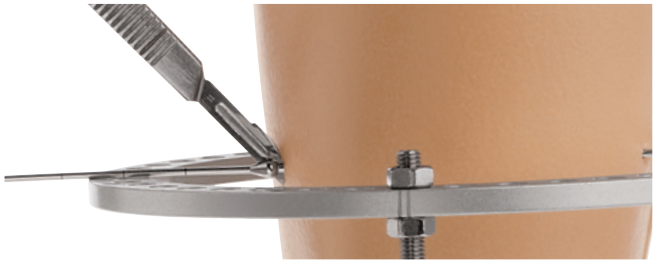


Fig. 24

5. If a stopper wire is used, make a small stab incision along the wire track **(Fig. 24)** to allow the bead to pass through the skin. Stopper wires are advanced until the bead contacts the bone cortex. This can be accomplished by pushing the wire with a power drill or pulling the opposite ends of the wire with pliers **(Fig. 25).**

Fig. 25

Securing the Wire
Secure both ends of the wire to the external support using wire fixation bolts. This must be done with a minimal amount of wire bending.

The wire may bisect a ring hole. In such cases, use the cannulated feature of the wire fixation bolt **(Fig. 26).** Slide the bolt over the wire, insert into the proper hole, and secure it to the ring using a 10mm nut. The head of the bolt must not be rotated relative to the axis of the wire to ensure that the wire remains straight. Use a 10mm wrench to hold the head of the bolt while tightening the nut.

The wire may be at the edge of a hole or between two holes. Use the slotted feature of the wire fixation bolt in these situations **(Fig. 27).**

The wire may be on the surface of the ring or at a distance away from the plane of the ring. This occurs when the wire is inserted parallel, but at a fixed distance away from the plane of the ring. This commonly occurs because the axis of the wire is slightly non-perpendicular to the bone segment axis. In these situations, fill the space between the ring and the wire with spacing washers **(Fig. 28)**, or use a post **(Fig. 29)**, to avoid wire bending. Place an appropriate number of washers onto the fixation element prior to wire fixation. Up to three 2mm washers may be used, depending on the thickness of the ring. A post should be used if more than three washers are required.

TrueLok Wire Tensioner
The TrueLok wire tensioner is a spring-loaded, forceps style instrument consisting of four functional elements. The tensioner head **(A)** has a unique sliding adapter that will allow the head to capture the wire fixation bolt when used in both the cannulated and slotted configurations. The neck **(B)** displays the wire tension scale, which is graduated from 50Kg to 130Kg. The scale has lines oriented horizontally to the axis of the neck, which are indexed to the graduated scale. When tensioning, the neck is incrementally pulled into the body **(C)**; the farther the neck is retracted, the greater the tension. Read the amount of tension achieved by noting the horizontal line (and indexed tension amount) visible just distal to the tensioner body **(Fig. 30a).** The final functional element is the locking bar **(D)** and handles. The locking bar is a spring loaded, serrated bar that will maintain the handles in a closed position. The TrueLok wire tensioner allows three choices of tensioner head **(Fig. 30b)**: a) tensioning directly off the wire bolt; b) long nose head to tension off the ring and c) short nose head to tension off the ring.

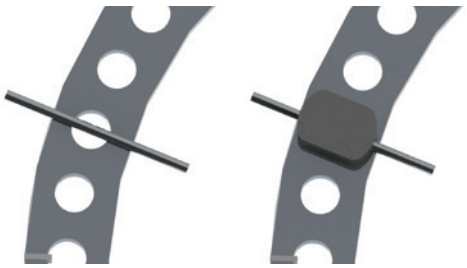


Fig. 26

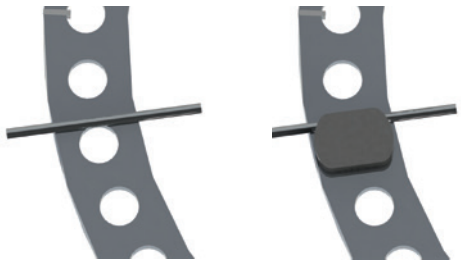


Fig. 27

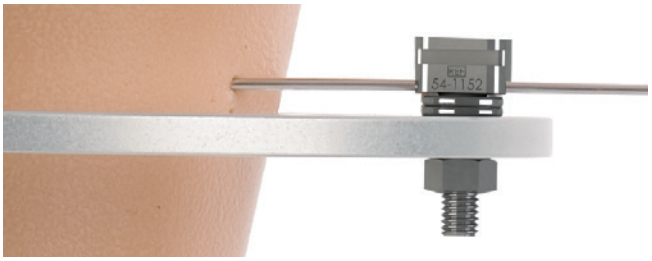


Fig. 28

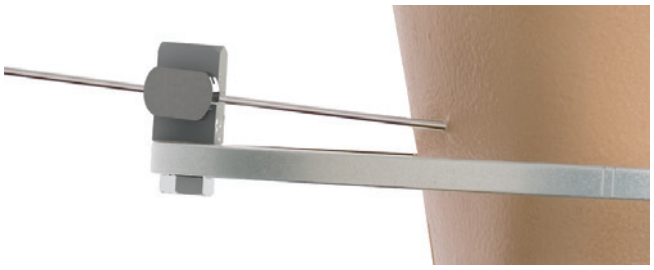


Fig. 29

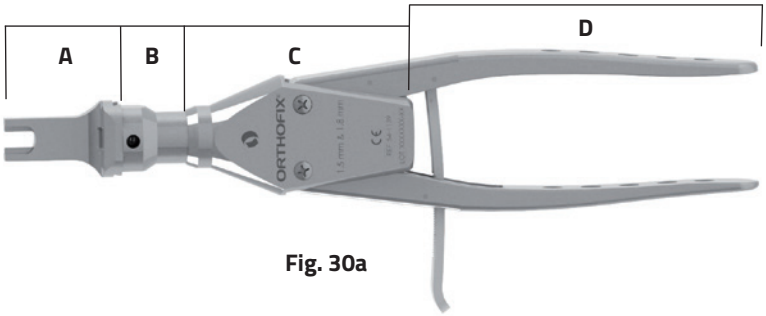


Fig. 30a

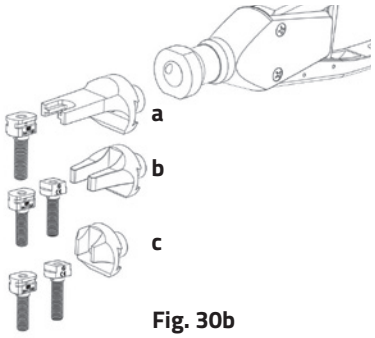


Fig. 30b

Tensioning the Wire
Tighten a wire fixation bolt on the wire to the ring on the side away from where the tension will be applied. Bend the end of the wire 90° to the plane of the ring **(Fig. 31).** This provides a quick visual clue that tension will be drawn on the opposite side.

Tensioning the wire involves drawing the wire against its fixed end. The level of tension applied varies with the clinical circumstances and individual preference. Typically, forces of between 100Kg and 130Kg are used.

Steps to tension a wire using the TrueLok wire tensioner:
1. Fully open the handles and slide the tensioner over the wire. Ensure the tensioner head captures the wire fixation bolt, and is firmly against the external support **(Fig. 32A).**
2. Squeeze the handles together until the desired amount of tension is generated. The wire tensioner locking bar will hold tension at a constant level **(Fig. 32B).**
3. Securely tighten the nut on the wire fixation bolt **(Fig. 33).**
4. Release the wire tensioner by depressing the locking bar and fully opening the handles. This disengages the wire tensioner jaws, and will allow the tensioner to slide off the wire **(Fig. 34)**.
5. Cut the wire ends flush with the frame avoiding sharp edges. Alternatively, to avoid causing injury, the ends of wires should be protected with special covers or bent at the ends as soon as they are tensioned.

Fig. 31

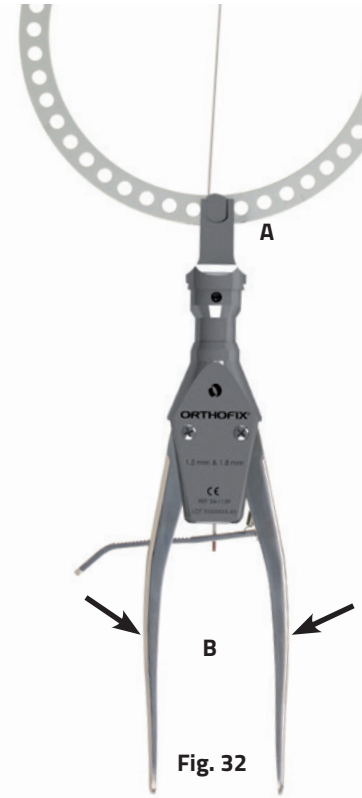


Fig. 32

Fig. 34

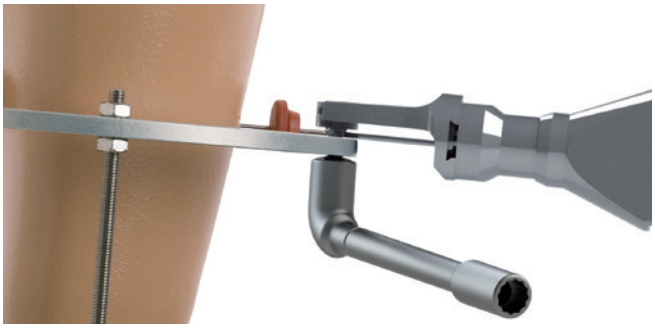


Fig. 33

The sequence of wire insertion and tensioning will vary depending on the specific nature of the disorder, frame application, and the surgeon's preference. In general, it is preferable to insert the most proximal and most distal wires, secure and center the apparatus to these wires, and then complete wire insertion and tensioning.

Simultaneously tensioning two wires on the same ring is advisable **(Fig. 35)**, since sequential tensioning may alter the tension of the initially tensioned wire.

Fig. 35

BASIC PRINCIPLES OF HALF PIN INSERTION AND FIXATION

Half Pin Insertion
with Universal Half Pin Fixation Bolt

The basic principles of aligning a ring on the limb perpendicular to its long axis remain the same when half pins are used instead of or in conjunction with wires. Furthermore, the half pin should be fixed to the ring in a manner that prevents any torque between the half pin and the ring by properly orienting the half pin fixation bolt to both the half pin and the ring. The use of half pins in place of wires, as well as their orientation and number, are at the discretion of the surgeon based upon training, knowledge of anatomic safe zones, and surgical preference.

The following steps outline the recommended method of half pin insertion and fixation:

1. A half pin fixation bolt is inserted into an appropriate hole. The half pin fixation bolt acts as a guide for half pin insertion **(Fig. 36).**
2. A K-wire is passed through the hole of the fixation bolt along the intended direction of the half pin insertion. Make a stab incision in the skin at this level **(Fig. 37).**
3. Use scissors or hemostats to make a track through the soft tissues to the bone.
4. The desired half pin is inserted through the fixation bolt, the soft tissue track, and drilled into the first bony cortex **(Fig. 38).** Insertion through the second cortex should be done manually using the T-wrench supplied in the set **(Fig. 39).**
5. The half pin fixation bolt is then secured firmly to the external support with a nut **(Fig. 40)**.
6. If the half pin is cut to length, Screw Covers should be used to protect the cut end.

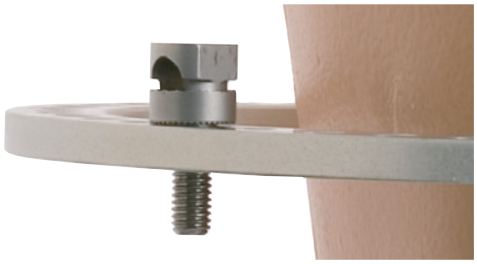


Fig. 36

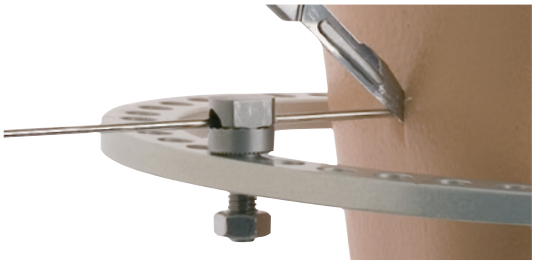


Fig. 37

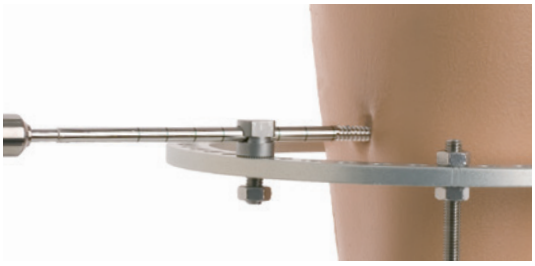


Fig. 38

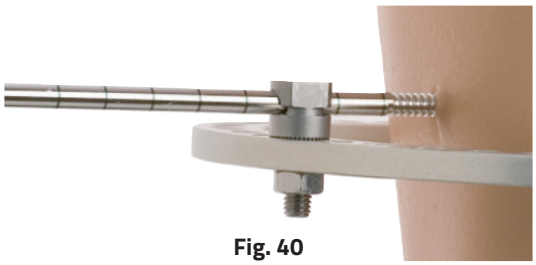


Fig. 40

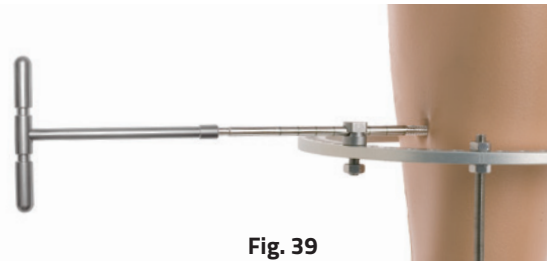


Fig. 39

Half Pin Insertion with the 8mm Half Pin Fixation Bolt

The following steps outline the recommended method of half pin insertion and fixation using the 8mm half pin insertion bolt:

1. Once the desired position is selected, a Screw Guide for 6mm shaft pin is inserted in the half pin fixation bolt through the dedicated groove in the collar (the one with no marks) **(Fig. 41)**.
2. The desired Drill Guide and drill bit (3.2mm or 4.8mm) is passed through the Screw Guide **(Fig. 42)**.
3. Remove the drill bit. The desired half pin is inserted through the fixation bolt and the Screw Guide until it engages the second cortex **(Fig. 43)**.
4. Remove the Screw Guide **(Fig. 44a, 44b)** and turn the 8mm half pin collar until the appropriate number (representing the shaft diameter) is aligned directly below the hole **(Fig. 45)**.

The 8mm Half Pin Bolt Wrench (54-11560) can be used to rotate the collar of the 8mm bolt between 5, 6 and 8mm when space is tight, e.g. when other fixation elements are in adjacent holes **(Fig. 44b)**.

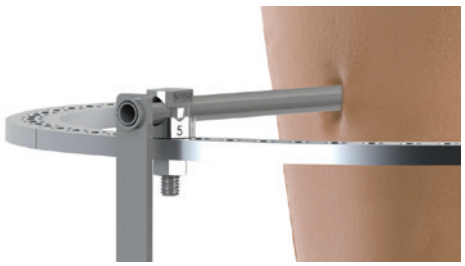


Fig. 41

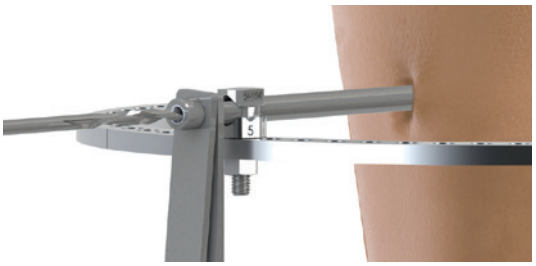


Fig. 42

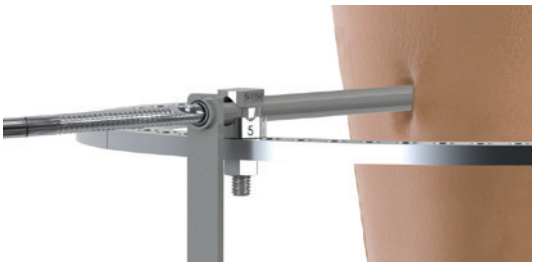


Fig. 43

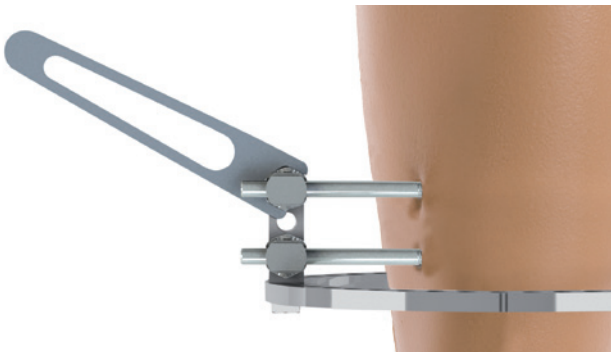


Fig. 44b

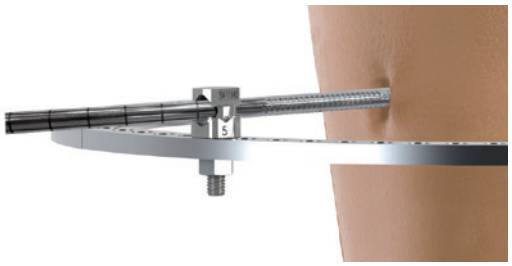


Fig. 44a

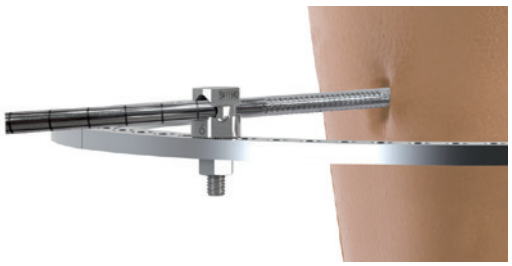


Fig. 45

Half Pin Orientation
When more than one half pin is to be secured to an external support, they should be spaced along the bone and around the circumference (i.e. one half pin should be on the proximal surface and one on the distal, or spaced at a distance using a post) **(Fig. 46).**

When half pin orientation is oblique to the plane of the ring, it should be attached using a post. To properly secure a half pin using a post:
1. Select the appropriate size post based on the distance from the half pin to the surface of the external support.
2. Loosely secure the half pin to the post with a half pin fixation bolt.
3. Loosely attach the post to the hole of the external support using a 12mm bolt.
4. Securely tighten the half pin to the post. Next, securely tighten the post to the external support, taking care not to bend or torque the half pin.

Fig. 46

USE OF RUBBER STOPPERS AND APPLICATOR

Rubber stoppers placed over wires and half pins are used to secure slotted gauze dressings for intraoperative and postoperative soft tissue compression. They should be applied right after wire and half pin insertion, prior to securing them to the external support. The rubber stopper applicator should be used for convenience and to prevent puncture injury to the surgeon. Red stoppers are used with wires. Grey stoppers are used with half pins.

The rubber stopper applicator is used as follows:
1. Press a stopper into the end of the applicator, flat side toward the skin **(Fig. 47).**
2. Insert a stopper over the end of a wire or half pin **(Fig. 48).**
3. Dislodge the stopper from the applicator with your thumb and slide the stopper down the wire or half pin to the skin **(Fig. 49).**
4. Repeat stopper application for remaining wires and half pins.

Fig. 47

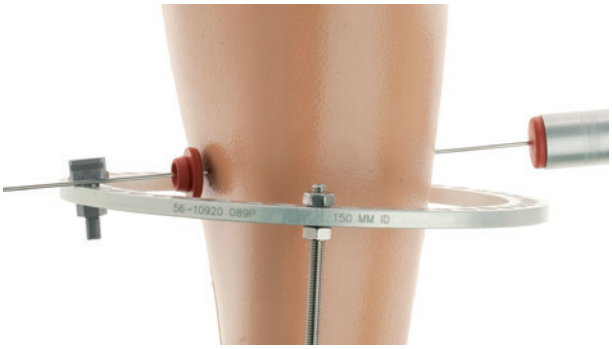


Fig. 48

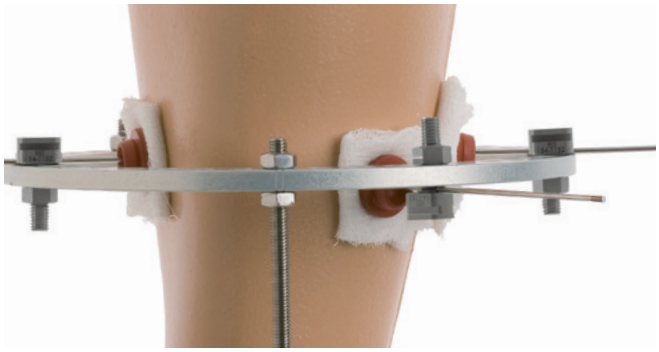


Fig. 50

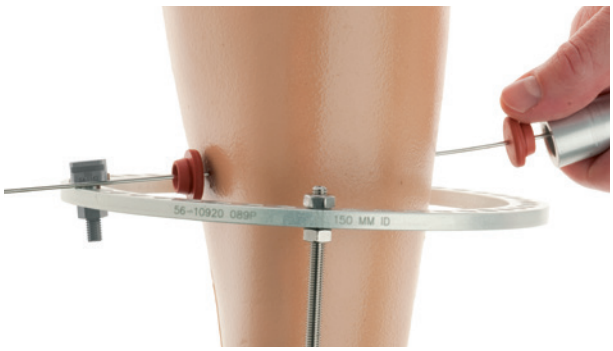


Fig. 49

Slotted 2x2 gauze dressings may be secured to the pin sites as desired intraoperatively or postoperatively **(Fig. 50).** Dressings are changed by sliding the stopper away from the skin, changing the dressing or performing pin site care as directed, and sliding the stopper back in to place.

If the stopper must be removed for any reason prior to frame removal, it may be cut to the center hole and removed from the wire or half pin.

TRUELOK CONNECTION ELEMENTS

The TrueLok set offers multiple connection elements, described below, to allow customizable frame construction based upon the clinical and anatomic considerations. The main purpose of these elements is to statically connect different external supports into fixation blocks.

Spacers
Spacers are used to create a ring block that is aligned, parallel, and has a short distance between rings **(Fig. 51).** Spacers are available in 15mm and 30mm lengths to provide a simple way to attach external supports to form a stable block. Spacers have male and female threaded ends, and a hexagonal center section that can be held with a 10mm wrench. To connect two rings, thread a 12mm bolt through the appropriate hole in the ring and into the female socket on the spacer. The male end is then secured to the second ring by a standard nut **(Fig. 52).**

Threaded Rods
A threaded rod is the standard element used to connect external supports. They are used to create a ring block that is aligned and parallel with a large separation between rings **(Fig. 53).** Rods contained in the TrueLok set have a 6mm outer diameter with a 1mm thread pitch, and come in a variety of lengths ranging from 60mm to 400mm. The threaded rod has a 1/8" (3.2mm) hexagonal socket cut in the exposed end for use with a standard 1/8" hexagonal wrench. When securing an element using nuts and a threaded rod, ensure the nut is a few thread lengths away from the end of the threaded rod so that it is on a full thickness of rod **(Fig. 54).**

Plates
TrueLok plates come in four lengths, ranging from 20mm to 50mm **(Fig. 55).** One end of the plate is a threaded hole, with serrations for greater rotational stability. The other end is either a single 7mm hole, or a slot, for greater adjustability. Plates provide the surgeon the ability to connect external supports in a parallel, non-aligned (short offset) configuration **(Fig. 56).**

Fig. 51

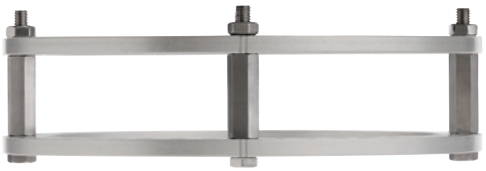


Fig. 52

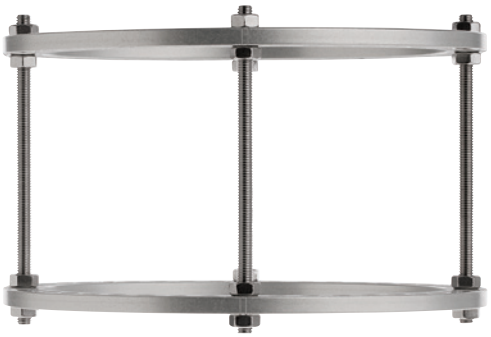


Fig. 53

Fig. 54

Fig. 55

Fig. 56

Oblique Support
An oblique support provides the ability to create a parallel, non-aligned (large offset) ring block **(Fig. 57).** The oblique support is useful for connecting arches or partial rings to full rings, especially at anatomic sites like the proximal humerus or proximal femur. One end of the oblique support has a threaded socket, while the other is a standard diameter hole.

Fig. 57

Conical Washer Couple
Conical washers provide the ability to build an aligned, non-parallel ring block. Each washer set consists of a washer with a convex side, and one with a concave side, forming a ball and socket. Washer sets should be placed on the threaded rod on each side of the ring, **(Fig. 58)** with the base of the concave washer against the ring surface, and the rod firmly secured at the desired angle with nuts. Placing a pair of conical washers on one ring of a block will provide angulation up to 7° **(Fig. 59).** Placing a pair on both rings provides angulation up to 14° **(Fig. 60).**

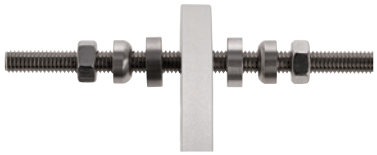


Fig. 58

Fig. 59

Fig. 60

Universal Hinge
A TrueLok universal hinge is a self aligning, versatile component providing 360° of motion **(Fig. 61A)**, which allows the surgeon to connect two supports at virtually any angle. It comes preassembled with short (35mm) studs. When longer threaded rods are needed to build customized frames, simply remove the stud using a 1/8" hexagonal driver and replace it with the bolt or desired threaded rod length **(Fig. 62).** The universal hinge can be locked in any position by tightening either a standard nut **(A)** or an external support **(B)** against the hinge housing.

Spherical Joint
The Spherical Joint is a versatile component that allows the surgeon to connect the dynamization module and external frame elements at virtually any angle up to 45° **(Fig. 61B)**. The Spherical Joint can be locked in any position by tightening a standard nut and an external support against the joint housing.


Fig. 61A


Fig. 61B

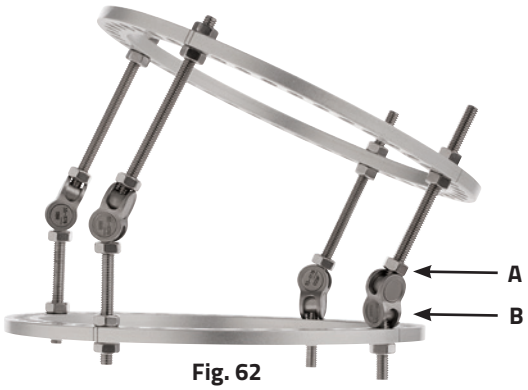
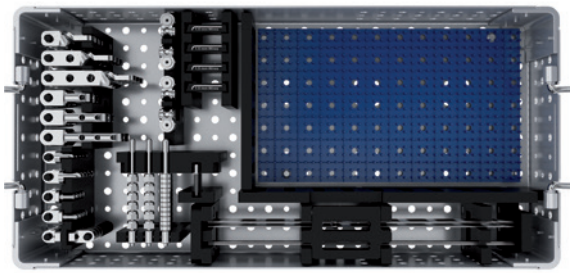


Fig. 62

(TL+) FOOT & ANKLE KIT

Part Number
450502



TL Plus Bayonet Wire with olive

Part Number	Size
54-1217	Ø 1.5mm x 300mm

TL Plus Bayonet Wire without olive

Part Number	Size
54-1218	Ø 1.5mm x 300mm

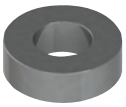
TL Plus Tension Limiter

Part Number
54-1141

The TL Plus Tension Limiter can be used with the TL Wire Tensioner to limit tension to 90kg when using 1.5mm diameter wires.

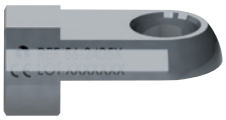
TL Plus Washer

Part Number
54-1143 **4mm Thick**



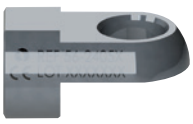
TL Plus Hinge Female High Profile

Part Number
56-24050



TL Plus Hinge Female Low Profile

Part Number
56-24051



TL Plus 90° Hinge High Profile

Part Number
56-24060

TL Plus 90° Hinge Low Profile

Part Number
56-24061

TL Plus Hinge Male High Profile

Part Number
56-24070

TL Plus Hinge Male Low Profile

Part Number
56-24071

TL Plus non Lockable Universal Joint

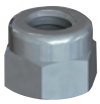
Part Number
51-10420

TL Plus Threaded Hinge Rod

Part Number	Length
51-10290	30mm

TL Plus Nylon Insert Nut

Part Number
50-1010



TL Plus Twisted Plate

Part Number	
54-11670	2 Holes
54-11680	3 Holes
54-11690	4 Holes

TL Plus 90° Plate

Part Number	
81641	1 Holes
81642	2 Holes
81643	3 Holes

TRUELOK HINGES AND ANGULAR DISTRACTORS

TrueLok hinges and angular distractors consist of internal and external components, which are designed to interface with each other to provide a constantly self-adjusting, stable angular correction system.

There are three types of cannulated hinges used for angular deformity correction: the Inline, the Outboard and the Phantom hinges. Inline and Outboard hinges are pre assembled and consist of a hinge base, a rotational insert, and a 100mm elliptical profile threaded rod that is secured in the insert with a Set Screw. The Phantom hinge is made of radiolucent material except for the metallic sleeve, which is radiopaque (see Phantom hinge section on page 21). The cannulated TrueLok hinges facilitate hinge axis alignment during frame application **(Fig. 63).**

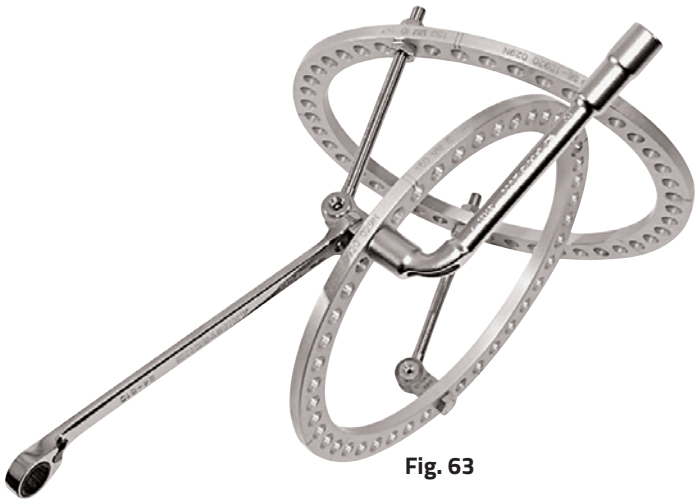


Fig. 63

Identifying the center of rotation (ankle)

To identify the approximate center of rotation of the tibio-talar joint, place the image intensifier in the medio-lateral (LAT) position and identify the curvature of the tarsus at the ankle joint. Draw a circumference that roughly follows the sinus of the tarsus **Fig 1a**. The center of rotation corresponds to the center of the circumference **Fig 1b**. Rotate the image intensifier by 90 degrees to have the vision in antero-posterior (AP).

During and after insertion of the wire, ensure their correct positioning under image intensification.

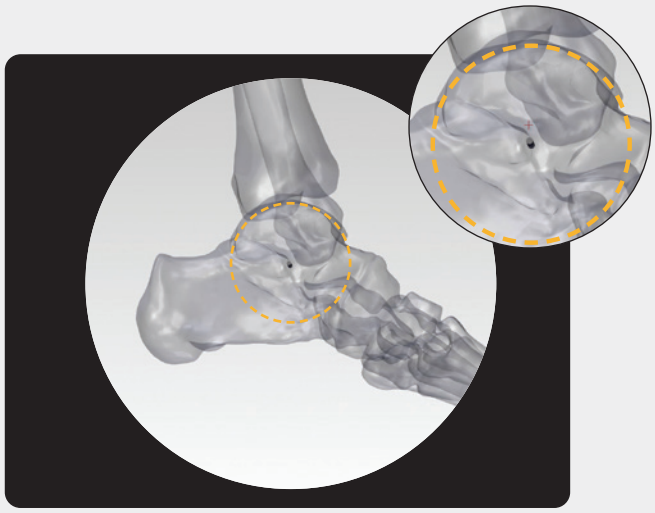


Fig. 1a - 1b

Inline Hinge
The inline hinge has a threaded hole at the base to accept either a fixation bolt **(Fig. 64)** or threaded rod **(Fig. 65)** for proper hinge axis location. The end of the threaded rod is secured to a ring in the traditional fashion with nuts as required for a specific assembly.

Outboard Hinge
The outboard hinge assembly is similar to the inline hinge, but the hinge base has a plate extension with a threaded hole to secure the hinge either directly to the ring with a 12mm bolt **(Fig. 66A)** or at a distance from the ring by using washers or a spacer **(Fig. 66B).** A 20mm plate is connected to the end threaded rod as part of the assembly to facilitate fixation to the adjacent ring **(Fig. 66C).**

Fig. 64

Fig. 65

Fig. 66A

Fig. 66B

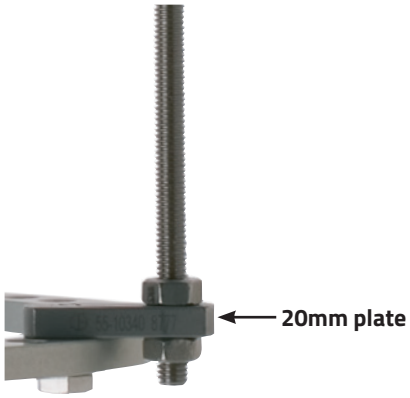


Fig. 66C

Additional Hinge Rods
Both inline and outboard hinges are assembled with 100mm elliptical profile threaded rods. Two additional sizes of threaded rods (60mm and 150mm) are available for hinge assemblies. They may be used in instances where a shorter or longer overall hinge length is desired.

To replace the elliptical profile threaded rod in the hinge assembly, the surgeon should loosen the Set Screw of the rotational insert **(Fig. 67A)**, pull the threaded rod out, **(Fig. 67B)**, replace it with the desired rod by inserting the elliptical end of this rod in to the rotational insert, and then tightening the Set Screw again.

Hinge Extender
When the length of threaded rod used in the hinge exceeds 150mm, the TrueLok hinge extender should be used to increase the length of the rod. The hinge extender may also be used to increase the overall rigidity of the frame structure **(Fig. 68).**

Angular Distractor
The TrueLok angular distractor **(Fig. 69)** consists of two distractor brackets **(C, F),** a special threaded rod **(D),** and a locking compression/distraction wheel **(E)**. The distractor brackets consist of two components that are held together with a Set Screw: the base and the arm **(Fig. 70 and 71).** The bracket base has a threaded hole to secure the hinge either directly to the ring with a 12mm bolt or at a distance from the ring by using a spacer. Each distractor bracket arm has a plastic insert **(B, G)** to interface with the bracket and threaded rod. One of the distractor bracket inserts **(G)** functions as a rotational socket, which interfaces with the end of the threaded rod. The other distractor bracket **(C)** has a threaded plastic insert, which interfaces with the threads on the rod. Each distractor bracket is able to pivot around the plastic insert, allowing the angle between the rings to adjust automatically as the distance between brackets changes. Multi-planar adjustments between the rings will be achieved by attaching each distractor bracket arm to the ring with a Swivel Stud **(51-10462)**.

Fig. 67A **Fig. 67B**

Fig. 68

Fig. 70

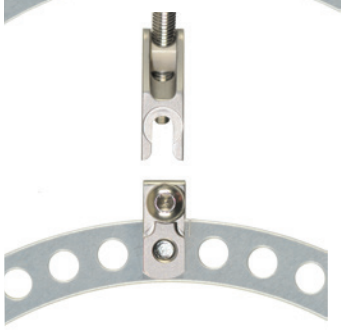
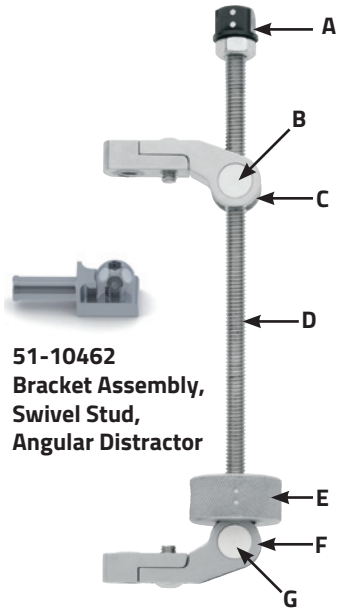


Fig. 71



51-10462
Bracket Assembly, Swivel Stud, Angular Distractor

Fig. 69

The compression/distraction wheel is a two-piece mechanism, which is locked to the threaded rod. The compression-distraction wheel has an outer collar and a central locking core. The outer collar is spring loaded over the locking core. The locking core has a square hole, which fits over the base of the distractor bracket preventing the wheel from turning. When the outer core is retracted, the knob is free to rotate **(Fig. 72)**. When the compression/distraction wheel is turned, the threaded rod rotates. When rotating, the rod end turns freely in the rotational socket, while the bracket with the threaded plastic insert is translated along the threaded rod **(Fig. 73)**.

A four-sided, 10mm nut **(Fig. 69A)** is fixed to the free end of the threaded rod. The dice markings on the nut provide a clear visual reference to monitor adjustments. The nut also provides an added safety measure by preventing the threaded rod from turning out of the bracket.

Quick Adjust Struts

Quick Adjust Struts are available in 3 sizes (short, medium and long) **(Fig. 74)**. They have a lockable universal hinge on both ends, which allows acute angular and rotational corrections **(Fig. 75)**. The strut's body consists of two telescoping aluminum tubes, an outer tube **(A)** and an inner tube **(B)**, which can be locked together at various lengths using the side locking bolt **(C)** and clamp washer **(D)**, thus allowing acute length adjustment.

The inner tube is attached to a square-sided plastic bushing **(E)**. The plastic bushing mates with the threaded rod **(F)** in a manner such that the rod moves relative to the aluminum tube when the plastic bushing is rotated, thus allowing for micro-compression or distraction. The four sided bushing is marked, similar to a dice, with 1, 2, 3, or 4 dots **(G)**. To provide distraction, turn progressively the bushing in the direction of increasing numbers on all struts (i.e. 1 to 2, 2 to 3, etc.). To provide compression, turn progressively the bushing in the direction of decreasing numbers on all struts (i.e. 4 to 3, 3 to 2, etc.). Secure the Quick Adjust Strut to the rings of the frame using a 12mm bolt.

Fig. 72

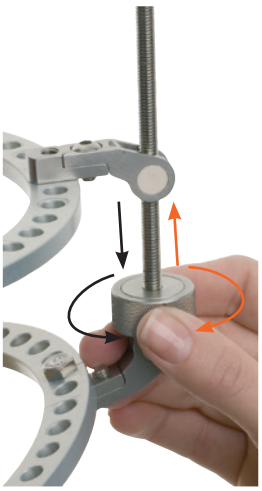


Fig. 73

Quick Adjust Struts

Part Number	Description
50-10170	Short
50-10180	Medium
50-10190	Long

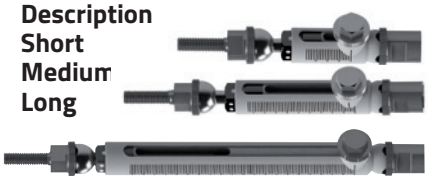
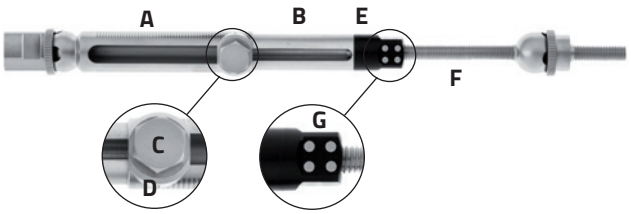
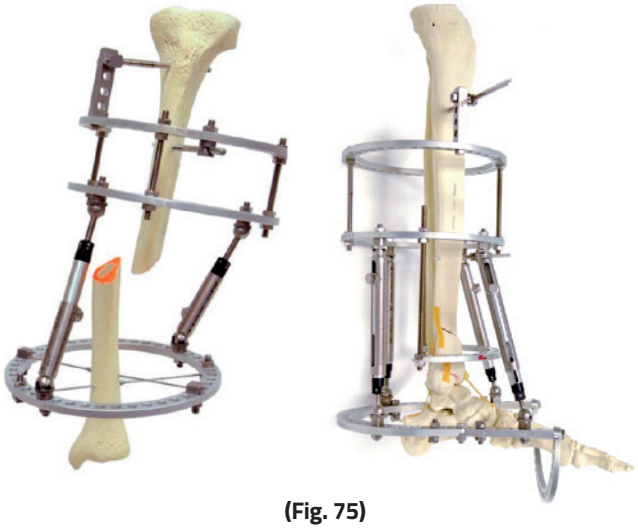


Fig. 74

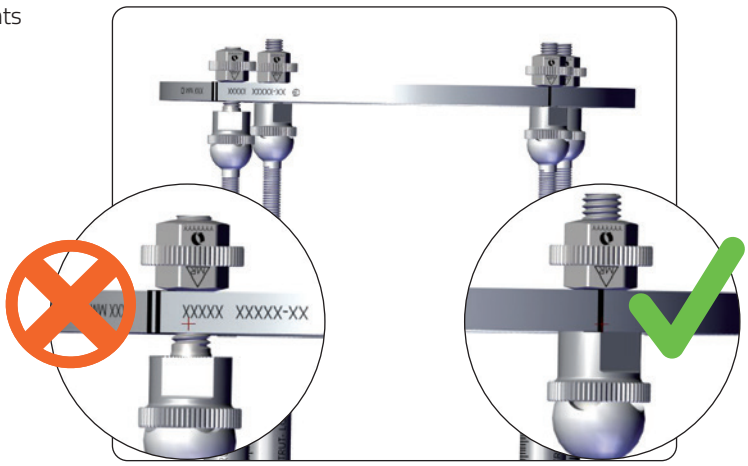
All Quick Adjust Struts are also available packaged sterile. They can be ordered using the above code numbers preceded by 99- (e.g. 99-50-10170).

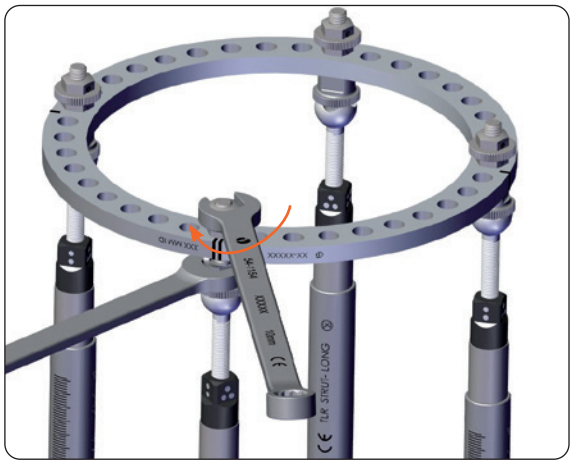




(Fig. 75)

Only tighten the central acute bolts after tightening the ball joints on both ends of the struts.

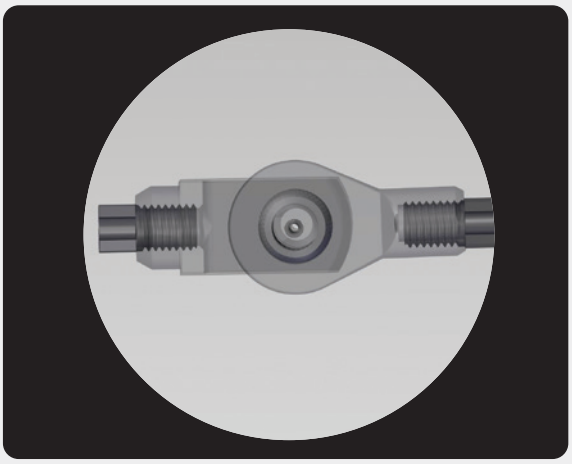


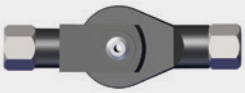


PHANTOM HINGE

The Phantom™ hinge is designed to interact with other components to provide a constantly self-adjusting, stable angular correction system along one plane (uniplanar hinges). It is made of radiolucent material, except for the metallic sleeve, which is radiopaque and facilitates, under X-Rays, the alignment of the axis of rotation of the joint with the hinges.

It is available in two sizes, a larger version specifically designed for knee applications and a smaller version for ankle applications.



	Part#	Description	Note
	99-50-2201M	TL Phantom Hinge Knee pack of 2	Sterile, 2 pieces per pack
	99-50-2202M	TL Phantom Hinge Ankle pack of 2	Sterile, 2 pieces per pack

KNEE APPLICATION - Assembly steps

The Phantom hinge has a threaded hole at the base to accept either a fixation bolt or threaded rod for proper hinge location. The end of the threaded rod is secured to a ring in the traditional fashion with nuts as required for a specific assembly.

STEP 1 - Femoral Ring Block

- Insert the femoral Ring block on the patient leg as shown in **Fig. 5**.

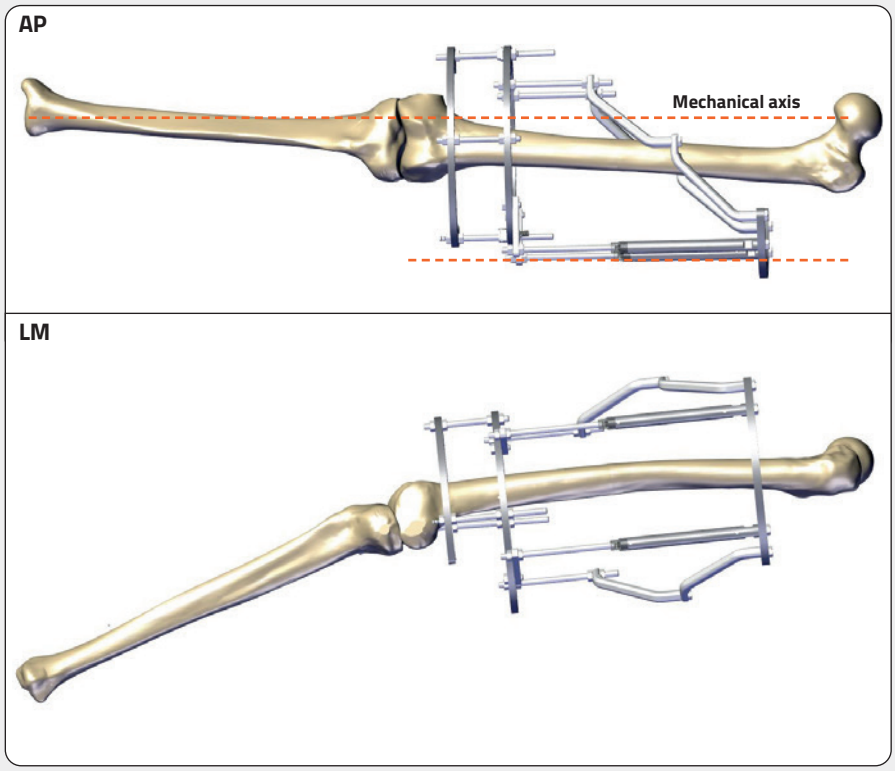


Fig. 5

STEP 2
REFERENCE WIRE PLACEMENT

- Draw a circumference that follows the profile of the posterior femoral condyle in sagittal section.
- The wire position is the center of the circumference.
- During and after insertion of the wire, ensure their correct positioning under image intensification.
- Insert a 1.8 mm diameter wire.
- Slide hinges on the wire and attach the hinges to the rings starting proximally **Fig. 6**.
- Connect the femoral ring Block.

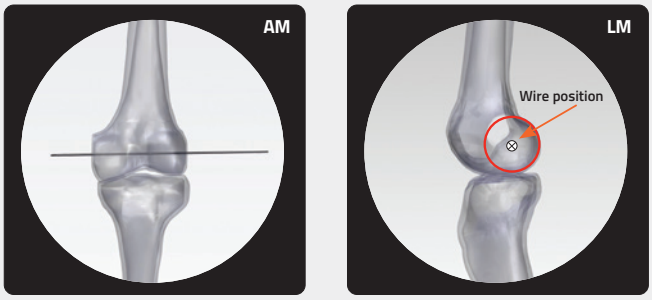


Fig. 6

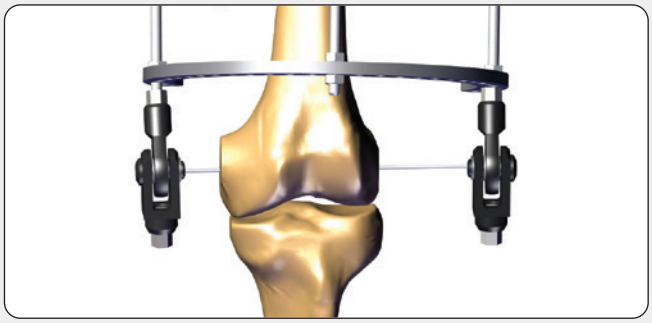


Fig. 7

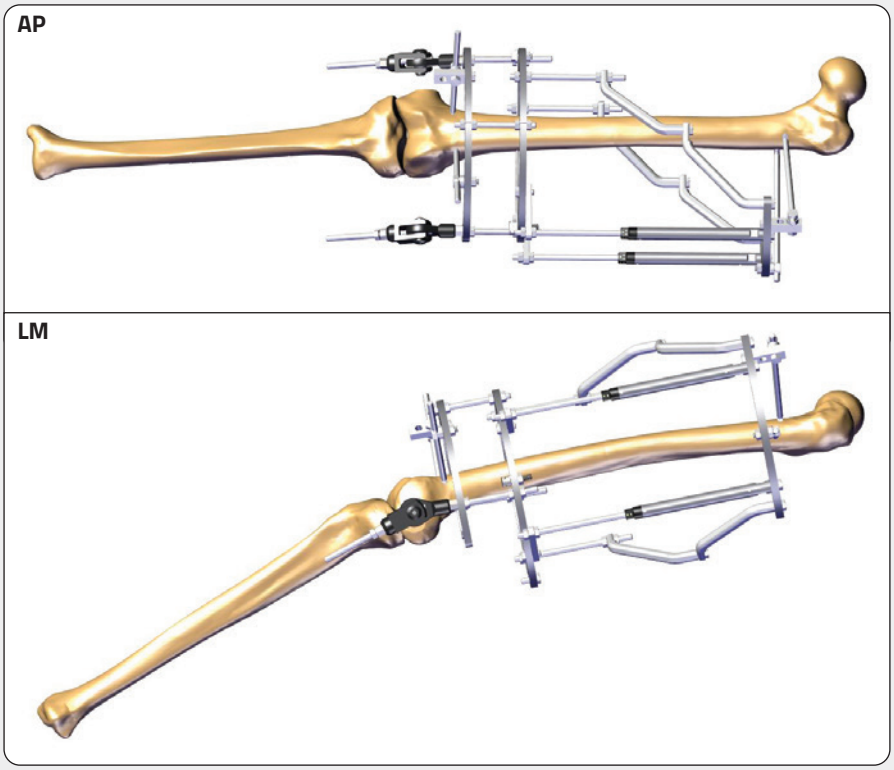


Fig. 8

STEP3 - Tibial Ring Block

- Position the tibial ring block **Fig. 9**.
- Attach the hinges to the rings and remove the wire from the Hinges **Fig.9**.

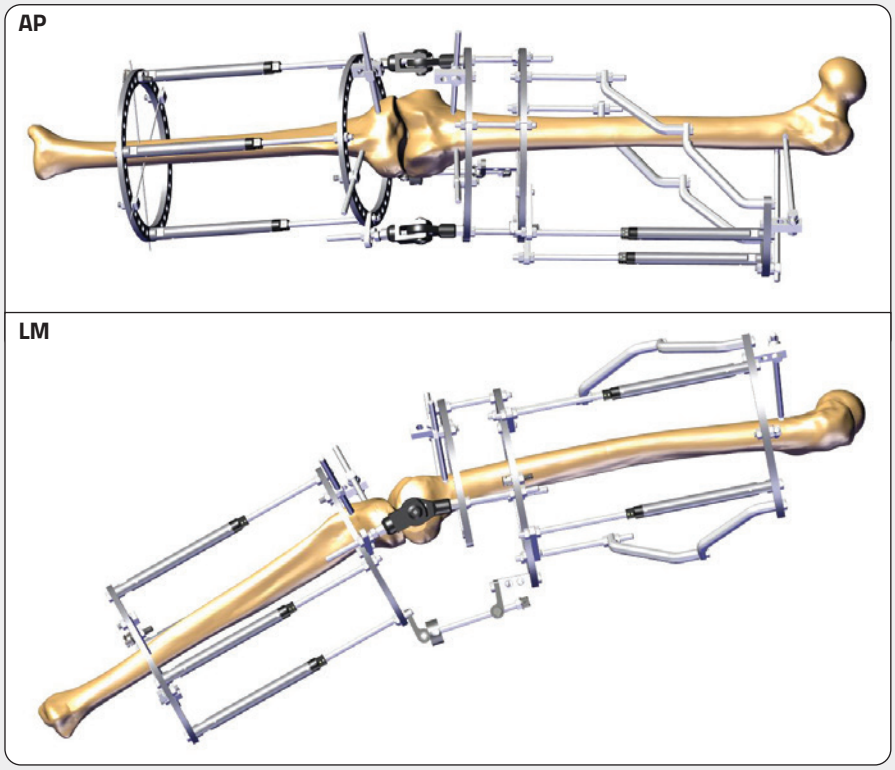
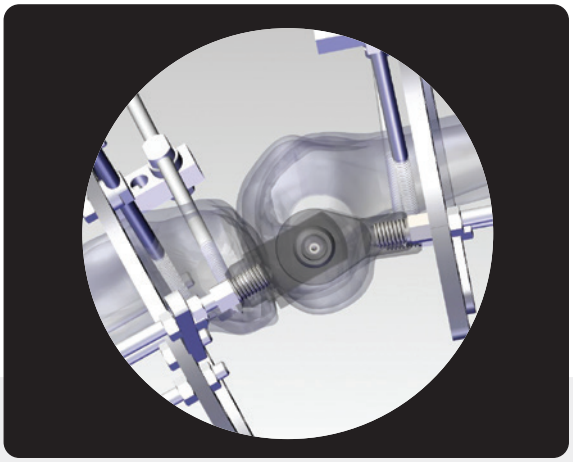


Fig. 9

- **When using the threaded rod, it must reach the endstop of the threaded hole of the metallic insert.** The 12 mm Bolt should be used with the conical washer (Code 54-1142).
- During assembly make sure that the frame is aligned to the mechanical axis.



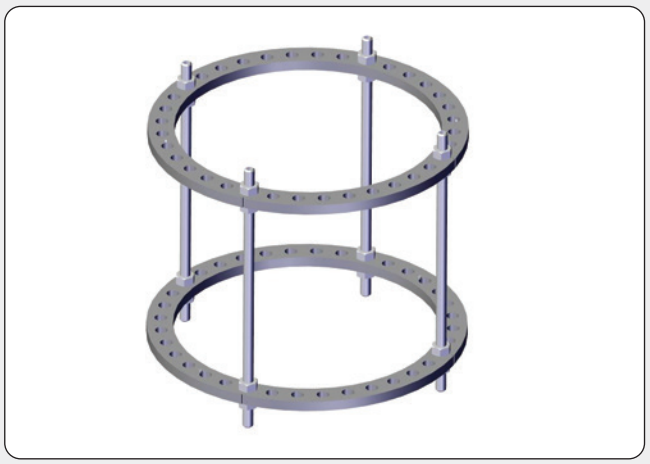
A washer is required when applying Phantom Hinges directly to TL-HEX™ or TrueLok™ EVO rings.

ANKLE APPLICATION - Assembly steps

The Phantom hinge has a threaded hole at the base to accept either a fixation bolt or threaded rod for proper hinge axis location. The end of the threaded rod is secured to a ring in the traditional fashion with nuts as required for a specific assembly.

STEP 1

- Insert the tibial ring block on the patient leg **(Fig 1)**.



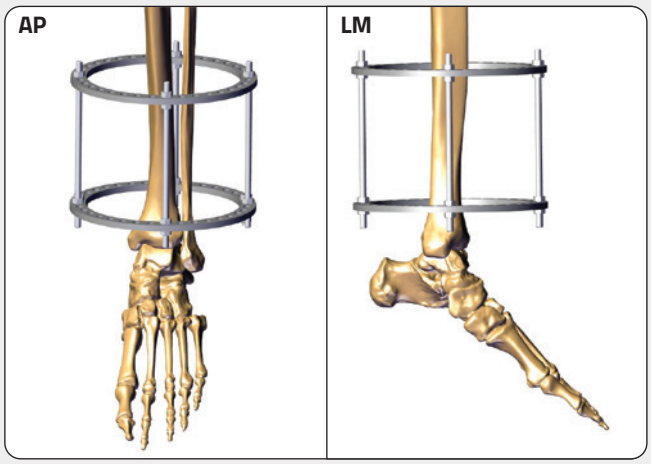


Fig. 1

STEP 2

- Identify the center of rotation and insert a K wire. See box "Identifying the center of rotation (ankle)" page 16.
- Slide hinges on the wires.
- Attach the hinges to the tibial ring as shown in **Fig. 2 and 3**.
- Place a reference wire on the plane to identify the correct direction and insert the guide wire parallel to the plane of the joint **(Fig 2)**.

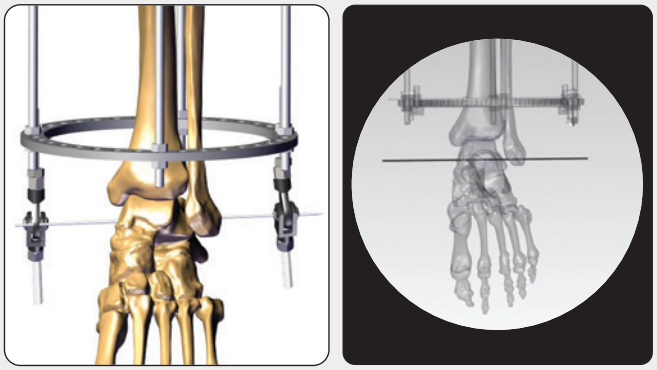


Fig. 2

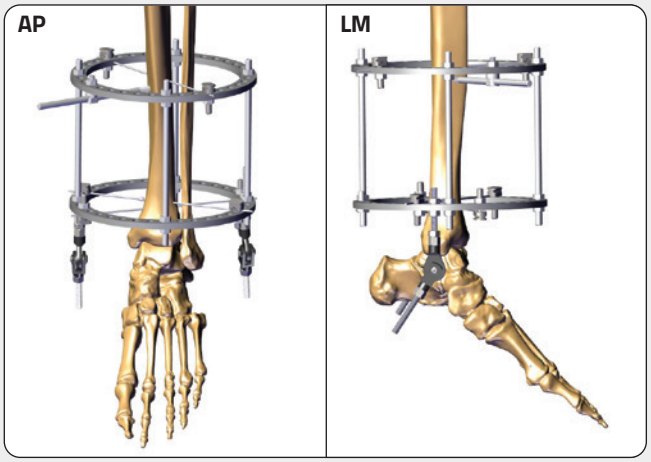


Fig. 3

STEP3

- Insert the foot ring block on the patient leg and attach the hinges.
- Remove the wire from the hinges.
- Complete the frame by adding the Angular Distractor code 51-10460 **(Fig. 4b,c)**.
- If joint distraction is needed, act on the threaded rod proximally. Foot orientation should be as shown in **Fig. 4**.

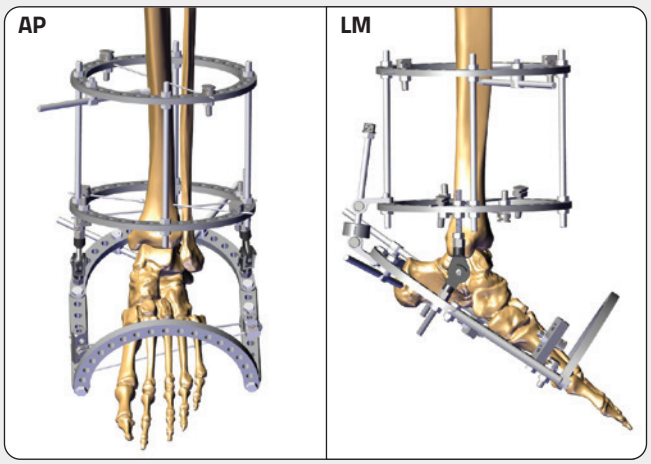
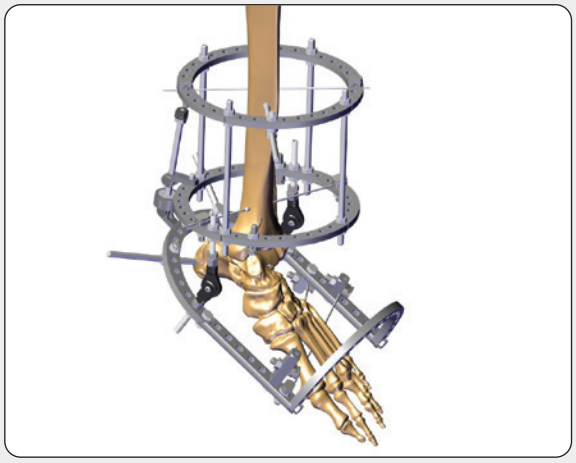
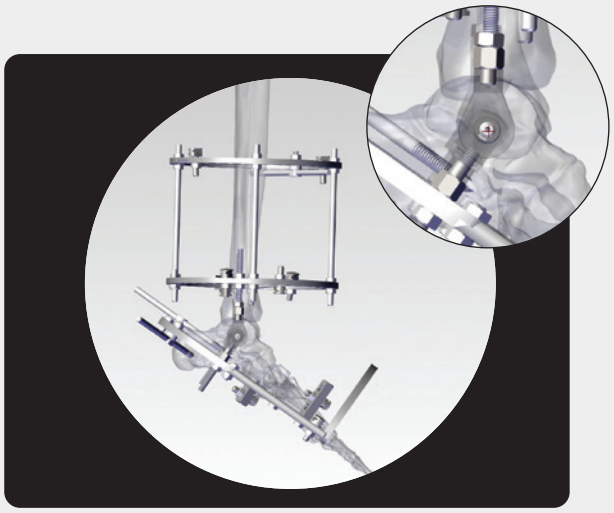


Fig. 4



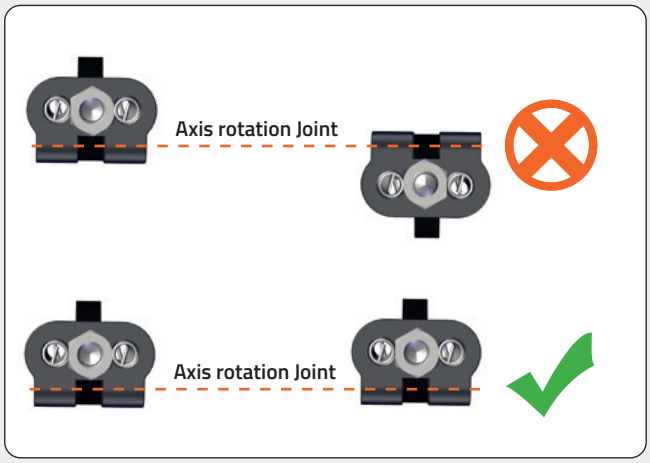


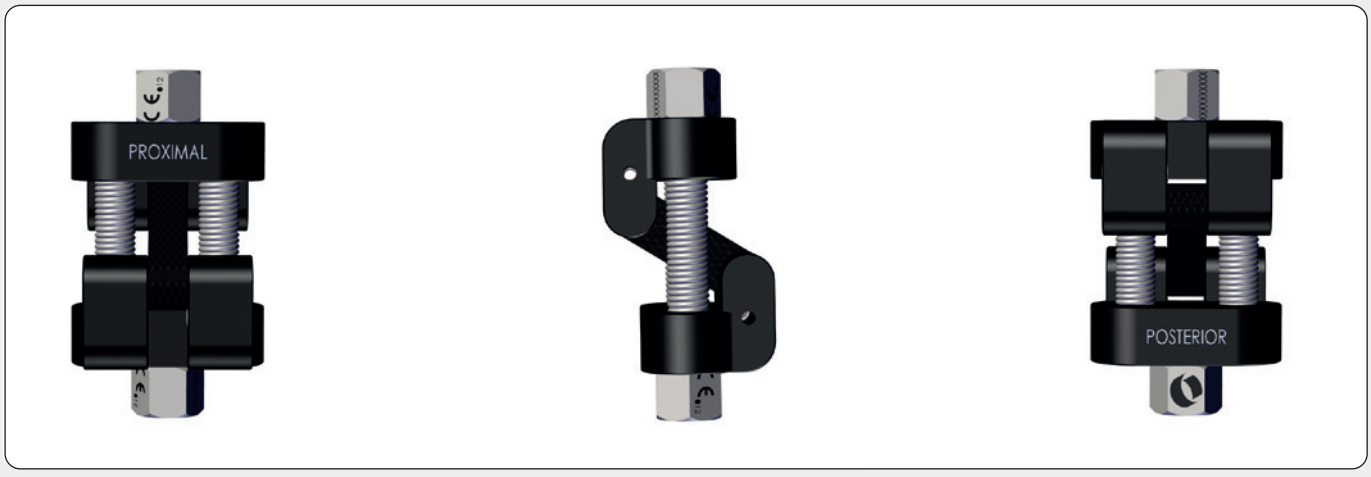
TORNADO HINGE

The TL-Tornado™ Hinge is a partially radiolucent mono-planar hinge that can be used when building a frame across a joint (such as knee and ankle) and allows the frame to rotate around the joint's axis of rotation. The Tornado Hinge is designed such that the position of its center of rotation moves depending on the rotation of the joint itself (polycentric).

	Part#	Description	Note
	99-50-2203M	TL Tornado Hinge pack of 2	Sterile, 2 pieces per pack

- **Some preliminary considerations to proceed with the correct assembly.**
- **Ensure that the Tornado Hinges are correctly positioned in order to be in the same direction with respect to the proximal and posterior positioning as marked on the device itself.**





KNEE APPLICATION - Assembly steps

For the use on the Knee Joint, the Tornado Hinge central spring has been designed to mimic the direction of the Anterior Cruciate Ligament (ACL) **Fig. 1**.

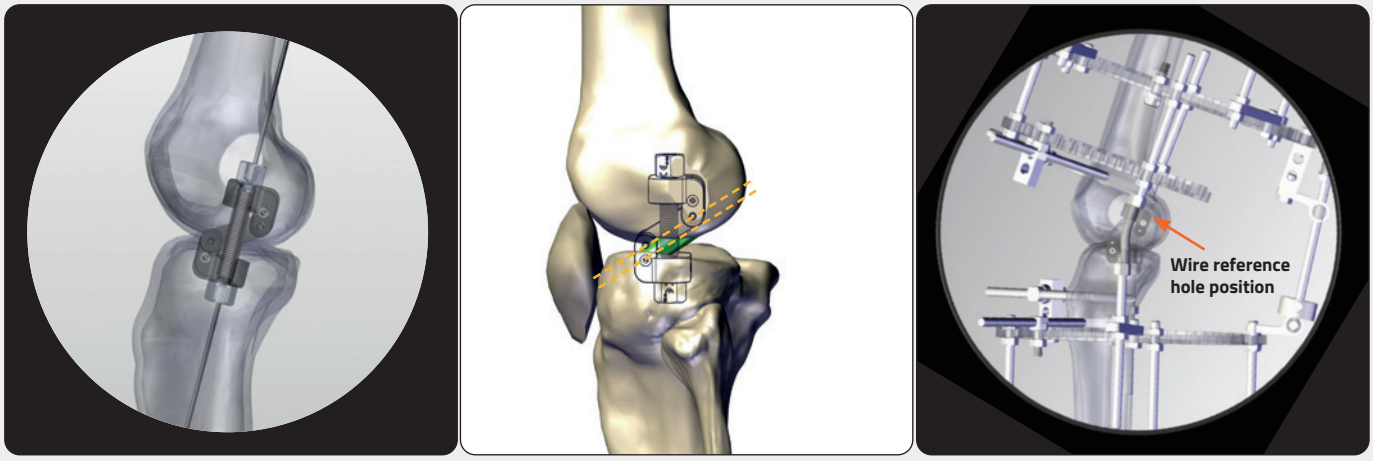


Fig. 1

STEP 1 - Femoral Ring Block

- Build femoral ring blocks **Fig. 2**.

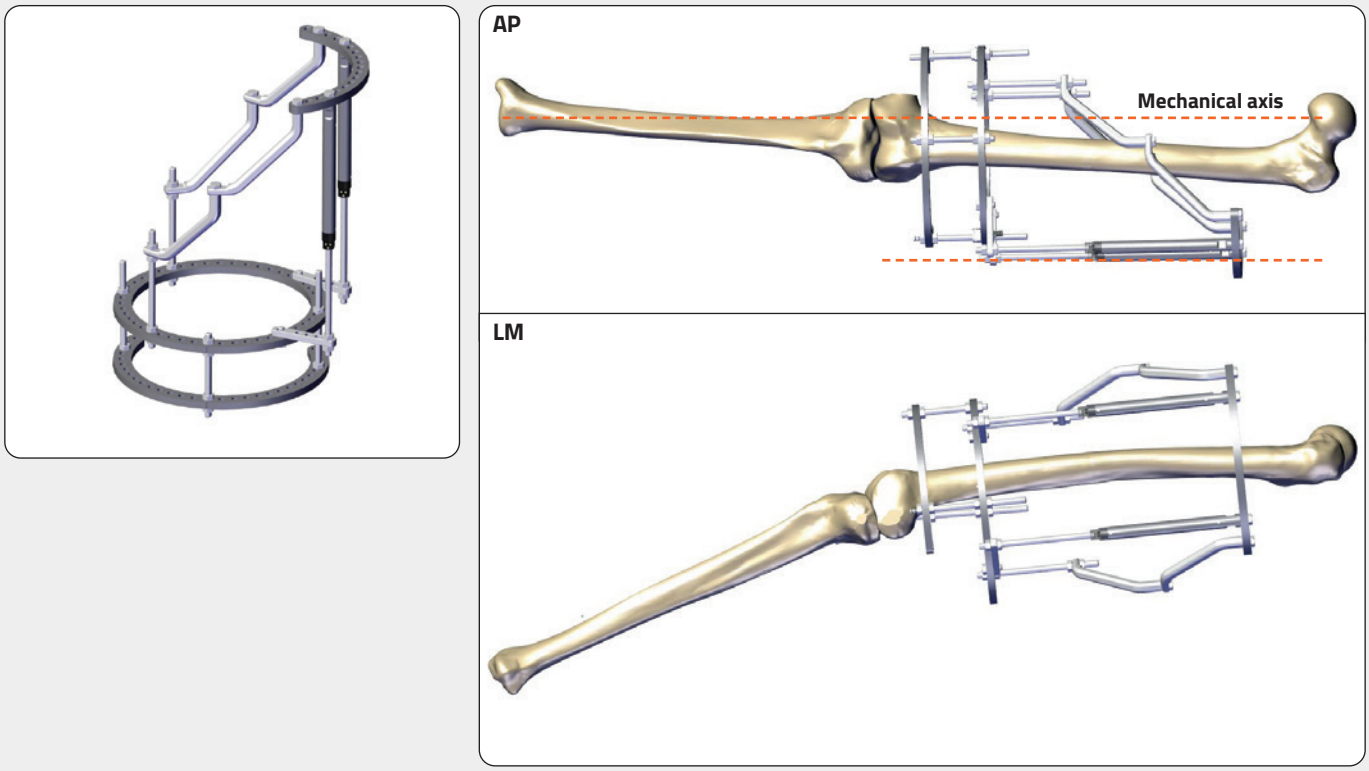
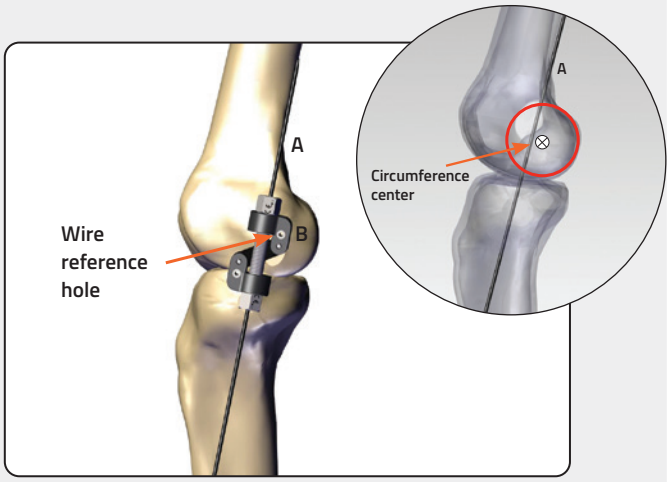


Fig. 2

STEP 2 - Hinges

Identify the axis of rotation of the knee.

- Use a K-wire against the skin to help identify the level of the posterior border of the femoral shaft (A).
- Identify the circumference of the posterior femoral condyles - the center of rotation lies at the center of this circle.
- Align the hinge spring to the posterior femoral wire (B) and match the posterior 'wire insertion hole' to the center of the circumference.



OPTIONAL STEPS

- A transcondylar wire, parallel to the joint on the AP view, can be inserted through this circumeference center to allow both hinges to be aligned with each other.
- During and after insertion of the wire, ensure its correct positioning under image intensification.
- Slide hinges on the wires.
- Attach the hinges to the rings starting proximally.

- Ensure that the Tornado Hinges are correctly positioned in the same direction with respect to the proximal and posterior positioning as marked on the device itself.
- Fix the femoral ring blocks to the Hinges.
- Apply the femoral ring Block ensuring that it is orthogonal into the mechanical axis in both the coronal and sagittal planes **Fig. 3**.

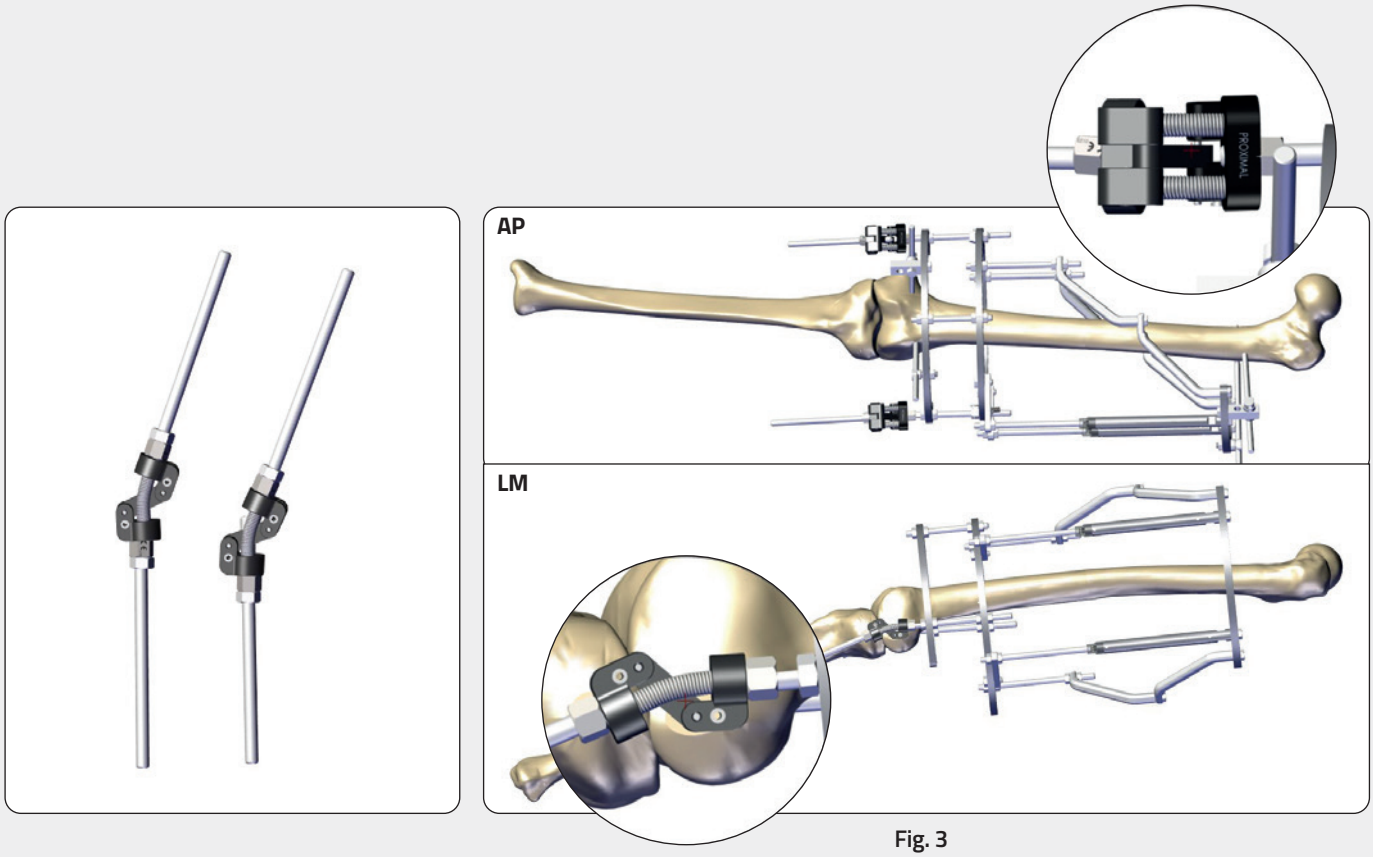


Fig. 3

STEP3 - Tibial ring Block

- Position the tibial ring block.
- During assembly make sure that the frame is aligned to the mechanical axis.
- In case the Tornado Hinge is not connected directly to the ring, add a lock nut to prevent rotation, either above or below the hinge.
- Attach the hinges to the rings and remove the wire from the hinges if one has been used **Fig. 4**.
- Complete the frame by adding the Angular Distractor (code 51-10460) **Fig 4**.

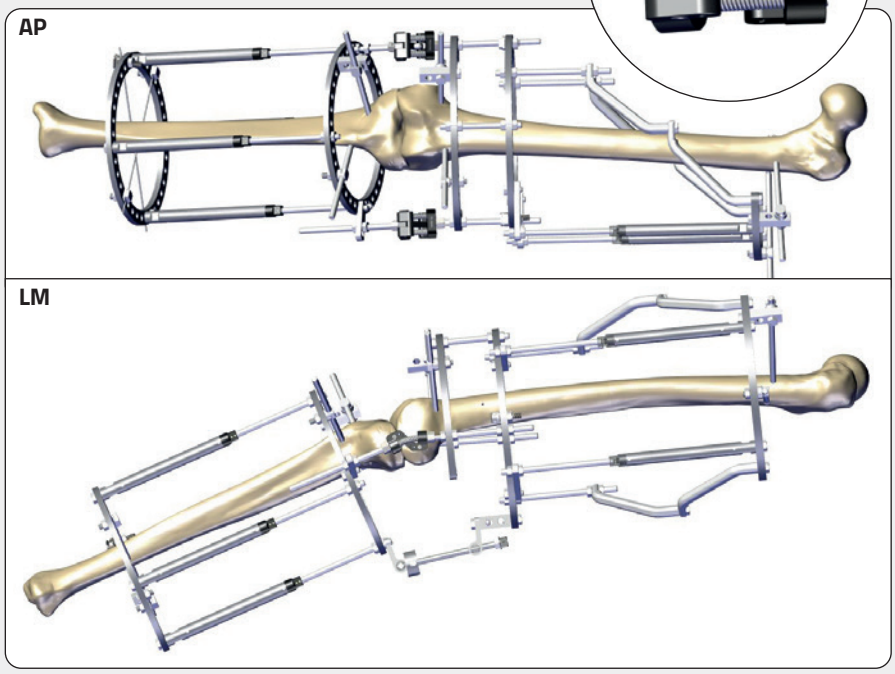
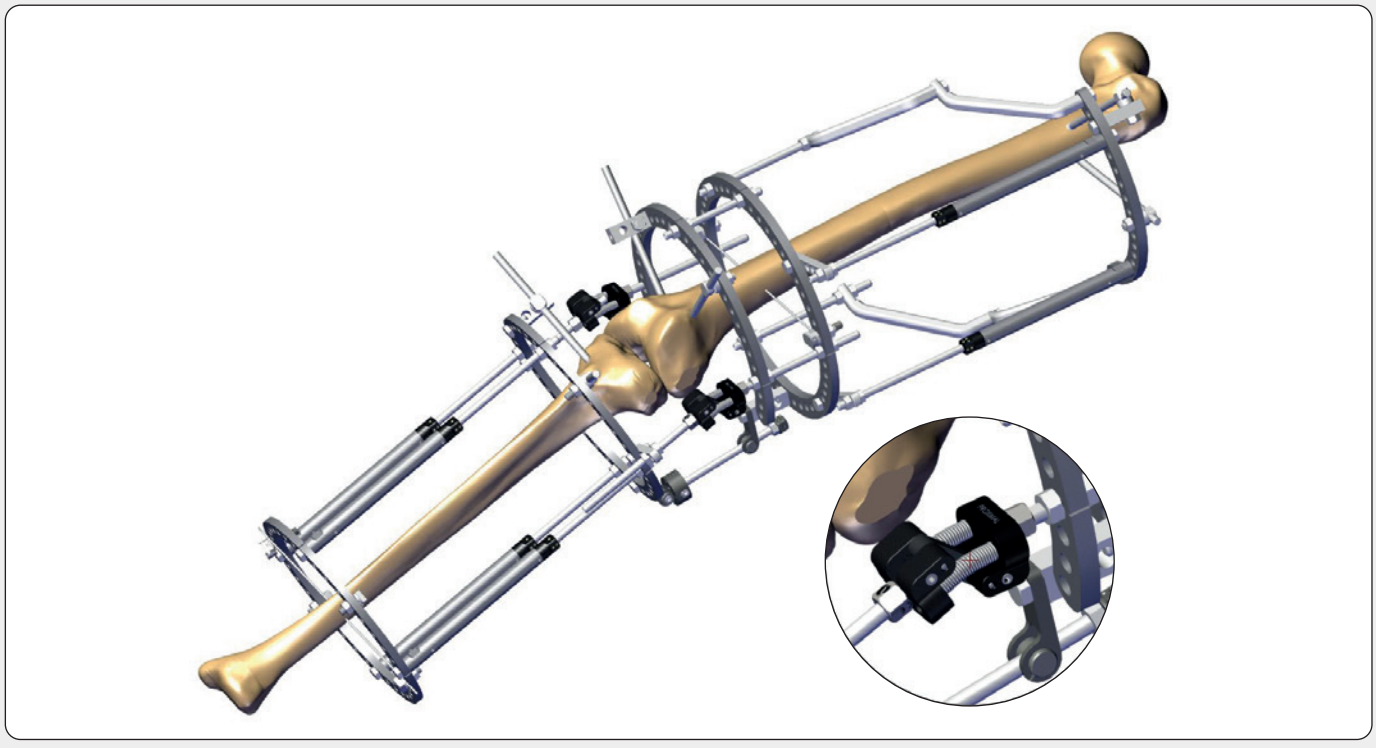


Fig. 4



ANKLE APPLICATION - Assembly steps

STEP 1 - Tibial Ring Block

- Insert the Tibial Ring Block on the patient leg **Fig. 1**.

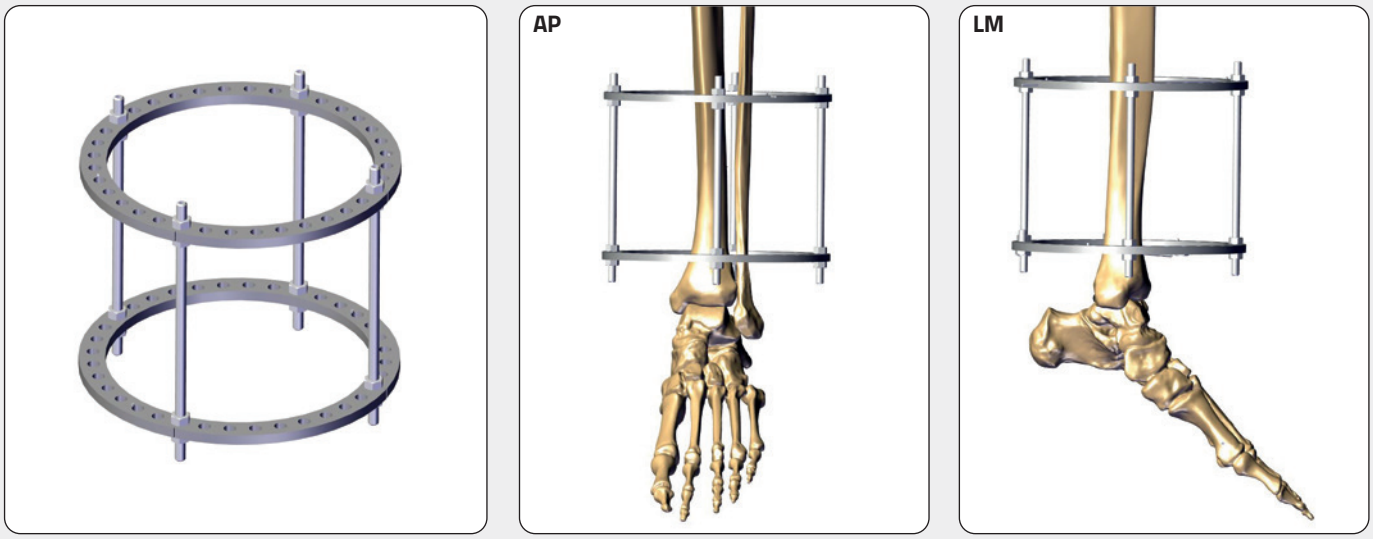


Fig. 1

STEP 2 - Hinges

- Identify the center of rotation. See box "Identifying the center of rotation (ankle)" **see page 16**.
- Align the central area of the Tornado Hinge spring with both the anatomical axis of the tibia and the ankle joint center of rotation **Fig. 2**.
- There is no need to pass a reference wire when using Tornado Hinges as the hinges adapt to the joint's normal axis of rotation (mark a reference on the patient's skin).

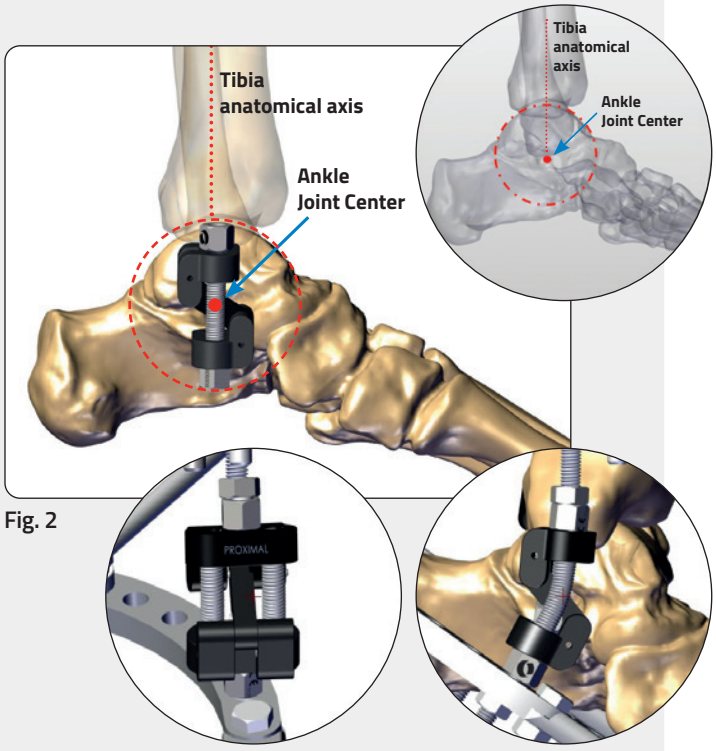
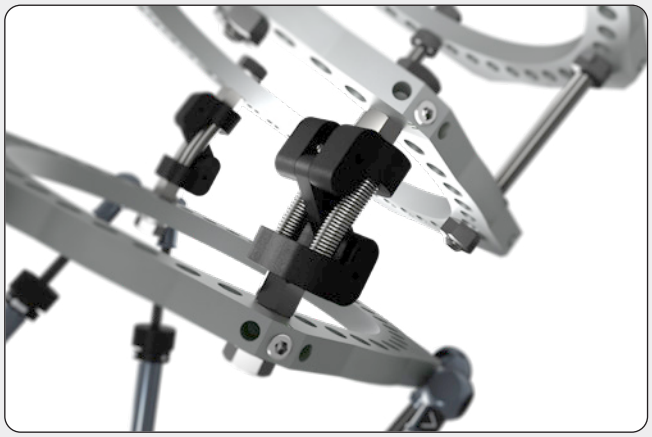
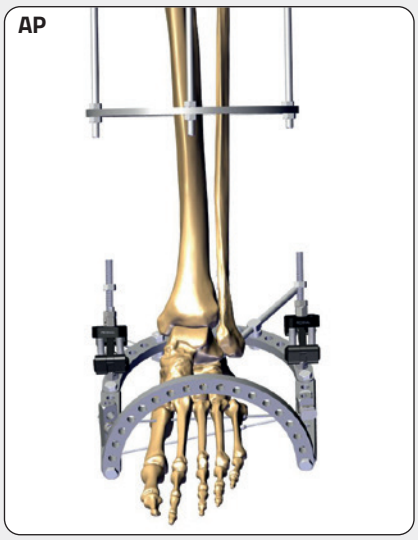


Fig. 2



A washer is required when applying Tornado Hinges directly to TL-HEX™ or TrueLok™ EVO rings.



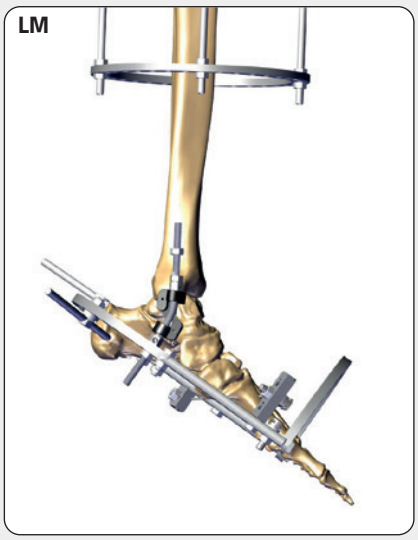


Fig. 3

STEP 3 - Foot plate

- Attach the foot frame to the distal ends of the Tornado Hinges and apply fixation to the foot **Fig. 3**.
- Attach the hinges to the foot plate as shown in **Fig. 3**. Ensuring that the long axis of the hinge is aligned to the anatomical axis of the tibia with the central area of the spring overlaying the axis of rotation of the ankle.
- Attach the hinges to the tibial ring as shown in **Fig. 4a**.
- Complete the frame by adding the Angular Distractor (code 51-10460).
- If joint distraction is needed lengthen the threaded rods between the tibial ring block and the Tornado Hinge body. Ensure that foot position is maintained in the frame and that the hinge remains in the optimal position after distraction **Fig. 4b**.

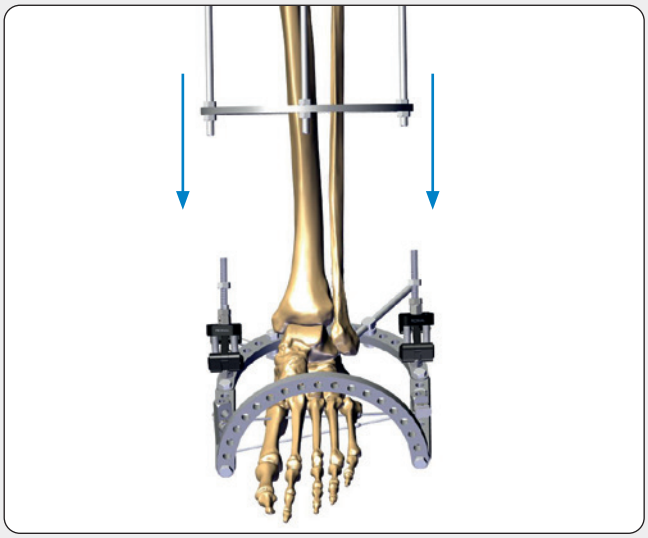
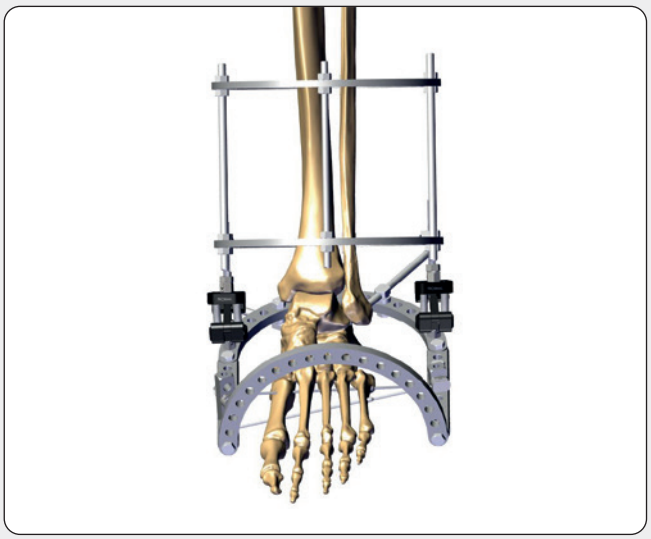


Fig 4a



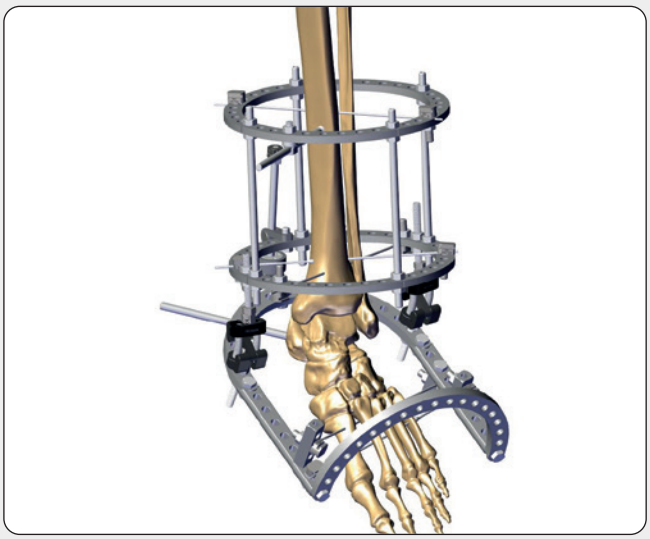


Fig. 4b

RING SIZING

Proper ring sizing is essential to avoid soft tissue compression by the apparatus during treatment. The surgeon must determine the proper ring size required based on the size of the limb. Use of the TrueLok sizing templates **(Fig. 76)** provides a simple and reliable way to determine the proper ring size. The ring diameter should allow approximately 4 cm of clearance between the diameter of the limb and the inner diameter of the ring.

Fig. 76

ANGULAR CORRECTION WITH TRUELOK HINGES AND ANGULAR DISTRACTOR

Proper use of a circular external fixator to correct angular deformities requires advanced skill in the application of the frame to the deformed limb segment. Pre-operative planning is essential to the successful correction of these deformities. The following steps are required:

1. The x-rays must be analyzed by the surgeon to determine the apex of the angular deformity. Inline hinges will normally be used to correct deformities where the axis of rotation will be between the rings of the frame. In such cases, a frame would be constructed for each bone segment, connected by two hinges centered at the apex of the deformity and an angular distractor on the opposite side. If a simple opening wedge correction is desired, the hinge apex must be placed at the cortex of the bone on the convex side of the apex of the deformity. If lengthening is desired in addition to opening wedge correction, the hinges should be placed beyond the cortex at the level of the apex.
2. The frame should be pre-constructed to mimic the deformity with the appropriate size and number of rings. The TrueLok hinges **(A)** and an angular distractor **(B)** are used to connect the non-parallel ring segments at the level of the deformity **(Fig. 77)**.
3. The pre-assembled frame should be checked on the patient's limb to ensure proper sizing and deformity analysis.
4. The deformity is corrected as a result of the osteotomy and the gradual distraction by the TrueLok angular distractor. **(Fig.s 78).**
5. Most surgeons design the distraction process so that when the rings are brought into a parallel relationship, the deformity has been corrected.

Frequently, the proper hinge location for correcting some specific deformities is at the level of the rings on one segment, or even further removed from the space between ring segments. For example, many pediatric deformities, such as Blount's Disease, have the apex of their deformity located at the growth plate. The outboard hinge, with its plate extension, allows for easy pre-operative frame assembly, which will properly correct these types of deformities **(Fig.s 79, 80).**

Pre-operative planning for correction of such deformities, including frame assembly, should be carried out as described previously. Proper location of the outboard hinge is dictated by the surgeon's evaluation of the deformity, the normal axis of the limb, and the amount of length desired. When a proper hinge location has been identified, the frame will be centered on the limb both proximally and distally.

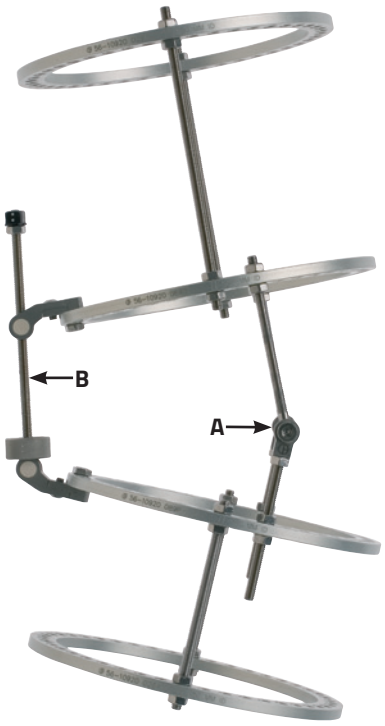


Fig. 77

Fig. 78

Fig. 79

Fig. 80

Frame Disassembly for Osteotomy Access
To provide access to the limb and ensure completion of the osteotomy, the hinges and angular distractor need to be temporarily disassembled. The angular distractor is disassembled by loosening the bracket Set Screws and removing the distractor body. Hinge disassembly is achieved by loosening the Set Screw on the rotational insert and the nuts on the end of the threaded rod. Loosen the nuts securing the ends of the hinge rods from their position on an external support's opposite end to allow them to retract **(Fig. 81).**

After the osteotomy is completed, the elliptical profile ends of the threaded rods of the hinges are reinserted in the rotational inserts, the Set Screws are tightened, and the ends of the threaded rods secured as they were before disassembly. The arms and bases of the angular distractor brackets are reassembled and the Set Screws tightened.

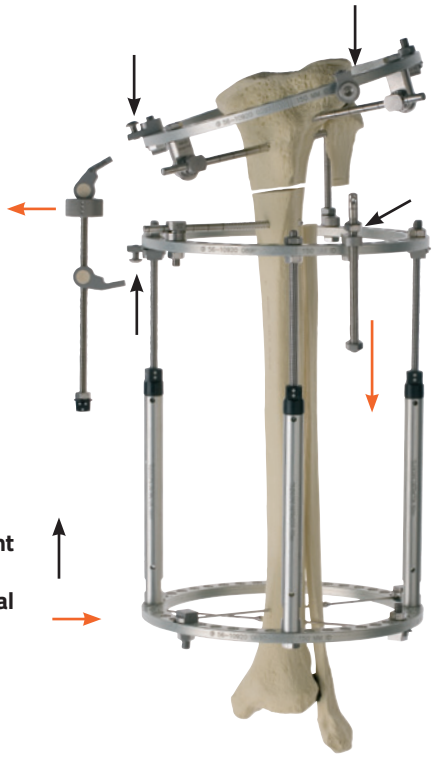


Fig. 81

Post-Operative Adjustment
The threaded rods supplied with the TrueLok system have a standard pitch of 1mm. Thus, each 360° of rotation of the compression/distraction wheel affects 1mm of distraction between the brackets. The actual amount of distraction required and the frequency are determined by the surgeon, based on the relationship of the hinges and angular distractor to the bone, and the quality of new bone formation within the distraction gap.

To operate the angular distractor the patient lifts the outer collar, rotates the compression/distraction wheel the desired amount, then allows the collar to spring back into a locked position.

Once angular deformity correction is complete, the hinges and angular distractor may be removed by the surgeon and the rings connected with threaded rods or other appropriate connection components.

TRUELOK LINEAR DISTRACTORS

Telescopic Linear Distractor
The TrueLok telescopic linear distractor **(Fig. 82)** consists of an aluminum tube **(C)**, which acts as the platform for a threaded rod **(A)**, and a square-sided plastic bushing **(B)**, which fits onto the aluminum platform in a manner such that it is able to turn freely on the aluminum tube. The threaded rod mates with the plastic bushing in a manner such that the rod moves relative to the aluminum tube when the plastic bushing is rotated. The threaded rod has a 1/8" (3.2mm) hexagonal socket cut in the exposed end for use with a standard 1/8" hexagonal wrench **(D)**, 90° hexagonal wrench **(E)** or power driver adapter **(F)** to facilitate rod length adjustment or threaded rod exchange.

When making a rapid rod length adjustment, use caution not to bottom out the rod in the distractor base or extract the threaded rod from the plastic bushing. If the threaded rod is completely visible in the hole of the base, a shorter linear distractor should be used.

The linear distractor should be replaced with a longer size if the threaded rod has reached the level of the hole at the top of the tube.

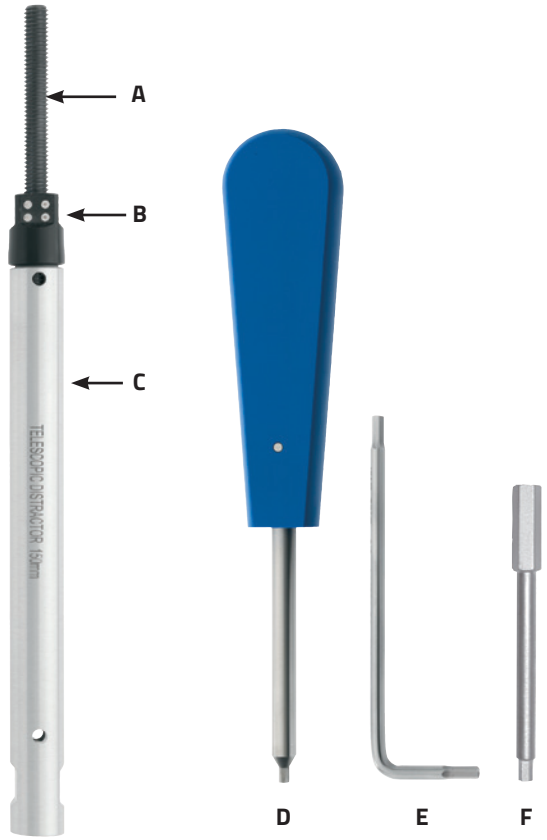


Fig. 82

Secure the linear distractor to the rings of the frame using a 12mm bolt at the base of the aluminum tube and nuts at the threaded rod **(Fig. 83).** The four sided bushing is marked, similar to a dice, with 1, 2, 3, or 4 dots **(A).** To increase the overall length of the distractor, and thus provide distraction, turn the bushing in the direction of increasing numbers (i.e. 1 to 2, 2 to 3, etc.) at the prescribed rate. To decrease the overall length of the distractor, thus providing compression, turn the bushing in the direction of decreasing numbers (i.e. 4 to 3, 3 to 2, etc.) at the prescribed rate.

TrueLok telescopic linear distractors are available in four sizes, requiring a minimal clearance of 75mm between rings and providing a maximum extension of up to 325mm **(Table 1)**.

Fig. 83

Table 1

MINIMAL CLEARANCE AND MAXIMAL EXTENSION OF THE TRUELOK LINEAR TELESCOPIC DISTRACTORS			
Part Number	**Description**	**Minimal Clearance**	**Maximal Extension**
50-11010	70mm Linear Distractor	75mm	90mm
50-10140	100mm Linear Distractor	105mm	145mm
50-10150	150mm Linear Distractor	155mm	225mm
50-10160	200mm Linear Distractor	205mm	325mm

All Linear Distractors are also available packaged sterile. They can be ordered using the above code numbers preceded by 99- (e.g. 99-50-11010).

DISTRACTION AND COMPRESSION WITH THE TRUELOK LINEAR DISTRACTORS

Limb Lengthening
Lengthening of limb segments to generate new bone tissue may be indicated for one of many disorders including congenital limb deficiencies, bone loss due to fracture, tumor and infection.

The surgeon must carefully assess the patient and the x-rays to ensure appropriate indications for lengthening of a limb segment. The proper ring size should be selected based on soft tissue considerations for each patient as previously described.

PRECAUTION: In patients undergoing callus distraction, the regenerate bone must be checked regularly and monitored radiologically.

The most common practice is to hold the ring segments together by using two telescopic linear distractors or threaded rods of the desired initial length attached directly anterior and posterior. This allows the distractors to serve as radiographic markers for proper alignment of the frame on the limb during surgery **(Fig. 84)**, while minimizing the chance that the distractor will occupy a ring hole required for wire or half pin fixation.

Fig. 84

After all bone fixation elements (wires and/or half pins) have been inserted and tensioned, these two distractors are replaced by four appropriately spaced distractors as desired by the surgeon **(Fig. 85)**. Placement of four distractors at the 1:30, 4:30, 7:30, and 10:30 (clockface) positions minimizes the interference of the radio-opaque distractors with the distraction bone regenerate on the radiographs.

After the frame has been assembled and secured to the bone, the bone is cut at the level and fashion desired by the surgeon. To confirm that complete bone division has occurred, the frame segments can be separated temporarily by removing the bolts at the base of the aluminum tube and slightly rotating one ring with respect to the other. These bolts are replaced after such confirmation has been achieved.

Post-Operative Adjustments
The initiation, rate, and rhythm of distraction are performed according to the surgeon's preference, and by the clinical situation. The patient affects the prescription by turning the square plastic bushing with a 10mm wrench.

Distraction of connected ring segments, and the associated limb lengthening, is achieved by rotating the plastic bushing by the prescribed amount. Each quarter revolution (90° turn) of the plastic bushing results in 0.25mm of distraction **(Fig.s 86 and 87)**. No other manipulations are required.

During lengthening, periodic x-rays should be studied to determine the length of the threaded rod remaining within the aluminum tube. Alternatively, the threaded rod may be viewed through a small hole in the aluminum tube at the base of the plastic bushing. **The linear distractor should be replaced with a longer size whenever the threaded rod has reached the level of the hole in the aluminum tube.**

When using the linear distractor to provide compression, the linear distractor should be replaced with a shorter size whenever the threaded rod is visible in the hole at the base of the tube.

Fig. 85

Fig. 86

Fig. 87

Square Distraction Nuts
As previously noted, the minimal clearance required between two rings to use a telescopic linear distractor is 75mm. In situations where the distance between two rings is less than 75mm, paired square distraction nuts **(Fig. 88)** may be used on a threaded rod to achieve either distraction or compression. The square distraction nut is a four-sided 10mm nut with a captured concave washer. For proper use, distraction nuts should be placed above and below the desired external support, with the concave washer against the support. The square distraction nuts should be aligned and tightened enough to stabilize the construct, yet allow for the paired nuts to be simultaneously turned using the double box wrench **(Fig.s 89, 90)**.

Fig. 88

SEGMENTAL BONE TRANSPORT

TrueLok square distraction nuts may be used for segmental axial bone transport. The limb is stabilized in a circular external fixator and a smaller segment of residual bone is transported within the limb until the defect has been traversed. The proximal and distal bone fragments may be fixed to rings with wires and half pins **(Fig. 91)**. The transport segment is separated from the host segment and attached to a transport ring with wires or half pins. Four threaded rods pass through each ring and are locked to the proximal and distal rings with standard metal nuts and the transport ring with square distraction nuts.

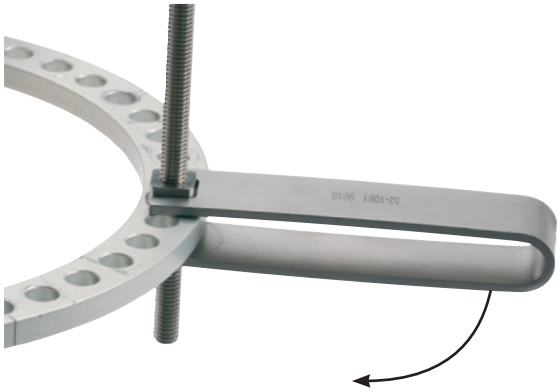


Fig. 89

Fig. 90

Bone transport is achieved by rotating the square distraction nuts. Each 90° rotation produces 0.25mm of axial bone transport. Repeat the distraction process per the surgeon's prescription until the transport bone segment reaches the target bone segment **(Fig. 92).** At this time, the bone ends at the docking site are prepared for bridging per the surgeon's preferred technique. Compression between the transport and target segments should be performed to help effect bony union.

HORIZONTAL TRANSLATION AND ROTATION

Three TrueLok threaded rods with square distraction nuts must be aligned transversely for use in horizontal translation or rotation. Each threaded rod is typically mounted on two posts connected to opposite rings. Turning the square distraction nuts one quarter turn results in 0.25mm of distraction or compression along the threaded rods, moving the bone segments horizontally by a comparable amount. For horizontal translation, all three rods are oriented in the direction of translation **(Fig.s 93, 94).**

In rotational correction TrueLok threaded rods with square distraction nuts are oriented in a triangular fashion **(Fig. 95).** As the square distraction nuts are turned, the rings are rotated relative to each other **(Fig. 96).**

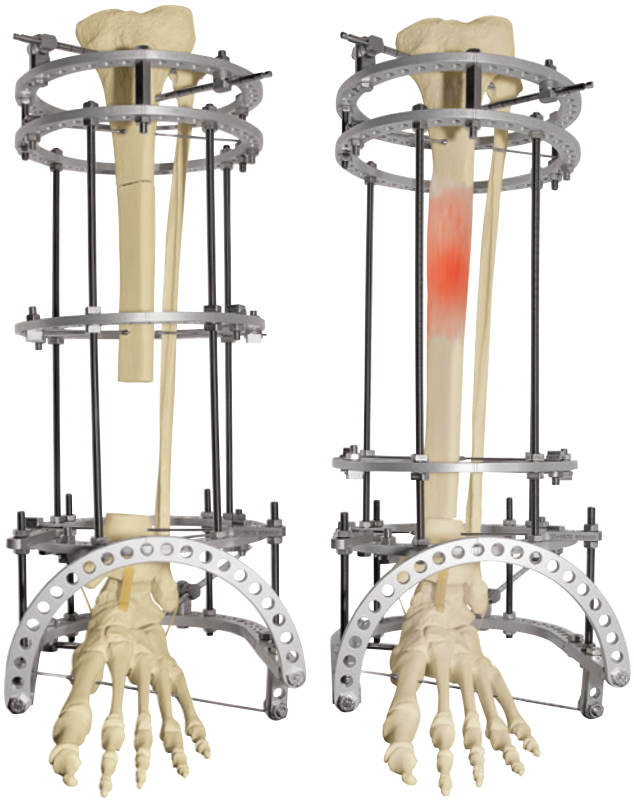


Fig. 91 **Fig. 92**

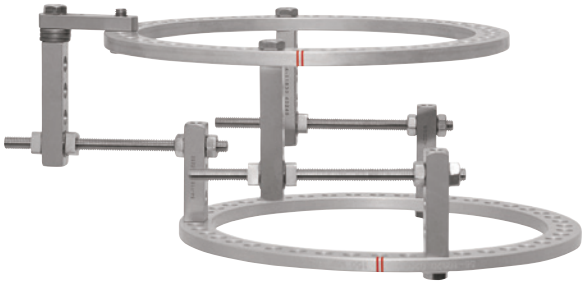


Fig. 93

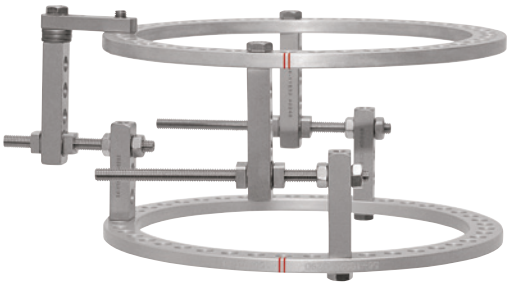


Fig. 94

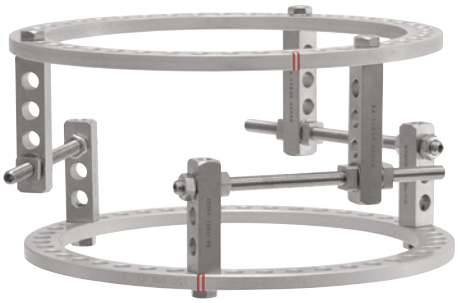


Fig. 95

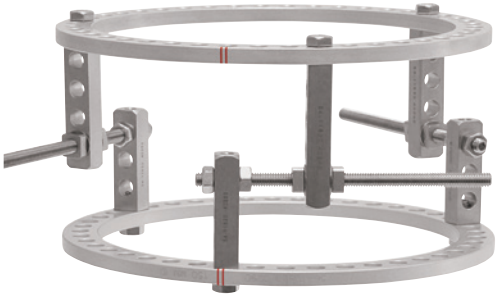


Fig. 96

TROUBLESHOOTING GUIDE FOR TRUELOK DISTRACTION NUT ASSEMBLIES

The double wrench does not slide easily over the two nuts:

The two nuts are not parallel **(Fig. 97).**

To correct, use one side of the wrench to bring the faces of the nuts into a parallel configuration. **(Fig. 98)**.

The double nuts do not turn easily:

The nuts may have been tightened too much.

To correct, loosen one nut by one quarter turn aligning the face of the nut parallel with the face of the other nut. Repeat this process until the nuts turn smoothly.

The double nuts turn too easily:

One square distraction nut is too loose.

To correct, tighten one nut until there is firm resistance against the ring, and the nut faces are parallel.

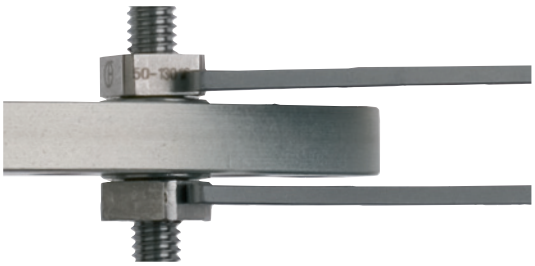


Fig. 97

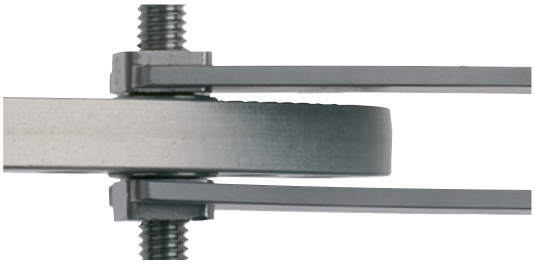


Fig. 98

SUGGESTED READING

M.V. Volkov, O.V. Oganesyan. *External Fixation: Joint Deformities and Bone Fractures*. 366 pages, International Universities Press, Madison, Connecticut, 1987

G.A. Ilizarov. *Transosseous Osteosynthesis. Theoretical and Clinical Aspects of the Regeneration and Growth of Tissue*. 800 pages, Springer-Verlag, New York-Berlin-Heidelberg, 1992

M.A. Catagni, V. Malzev, A. Kirienko. *Advances in Ilizarov Apparatus Assembly*. 155 pages, Medicalplastic, Milan, Italy, 1994

A. Kirienko, A. Vila, J.H. Calhoun. *Ilizarov Technique for Complex Foot and Ankle Deformities*. 459 pages, Marcel Dekker, New York, 2004

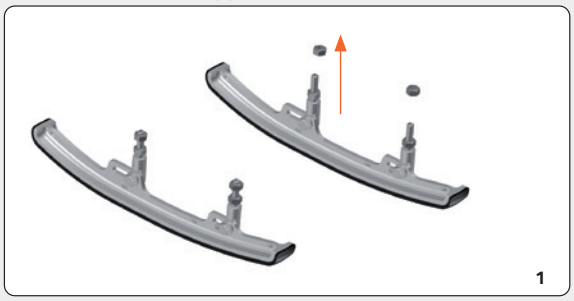
S.R. Rozbruch, S. Ilizarova. *Limb Lengthening and Reconstruction Surgery*. 695 pages, Informa Healthcare, New York, 2007

D. Paley. *Principles of Deformity Correction*. 806 pages, Springer-Verlag, New York-Berlin-Heidelberg, 2002

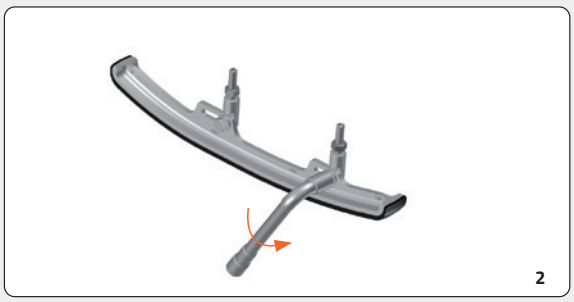
TRUELOK™ ROCKERRAIL

A. The TrueLok RockerRail is compatible with TrueLok and TL-HEX™ Foot Plates
B. Patient should be warned about hazard related to slippage.
C. For important medical information and maintenance consult Instructions for Use PQ TLK
D. Steam sterilization not allowed
E. Remove the caps from both RockerRail ends before application

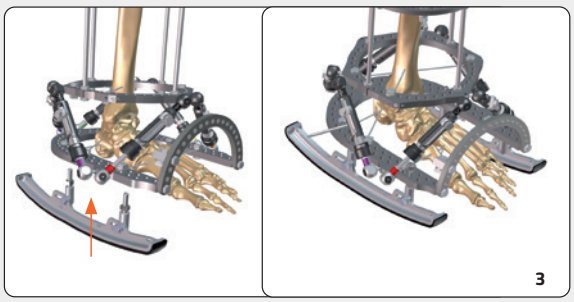
TrueLok RockerRail Application



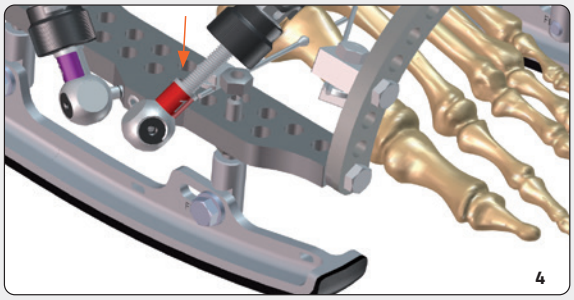
1. Remove the outer locking nut from the fixation rods on the rails



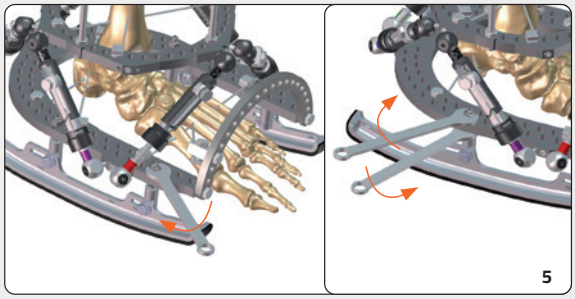
2. Loosen the adjustable sliding fixation



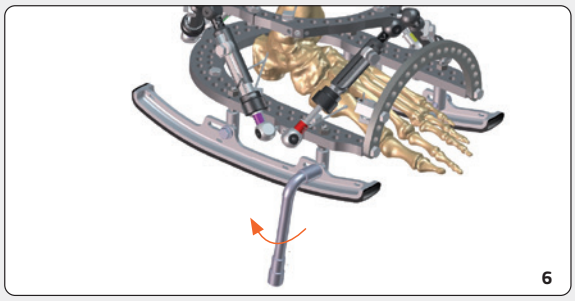
3. Place the TrueLok RockerRail with the FRONT marking anteriorly onto the Foot Plate by inserting its fixation rods into the appropriate holes



4. Place locking nuts back onto the fixation rods of the rails

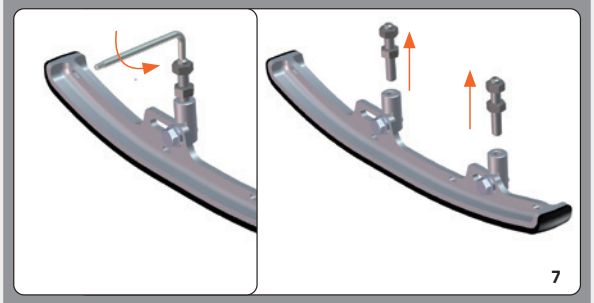


5. Use two 10mm wrenches to lock the rails onto the Foot Plate firmly

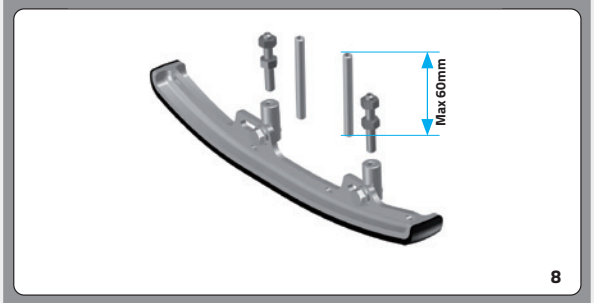


6. The rails should be adjusted as needed for ideal placement. Lock the adjustable sliding fixation

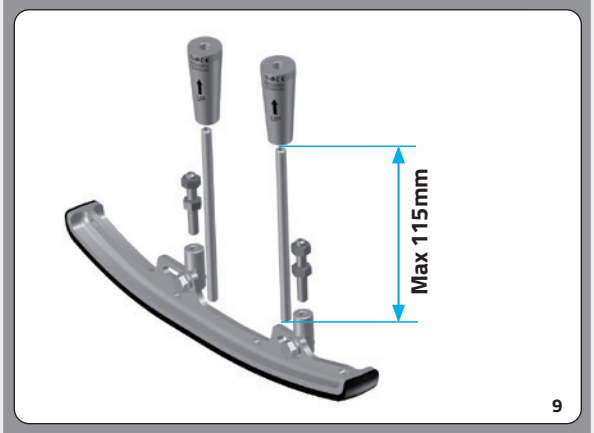
TrueLok RockerRail Height Adjustment



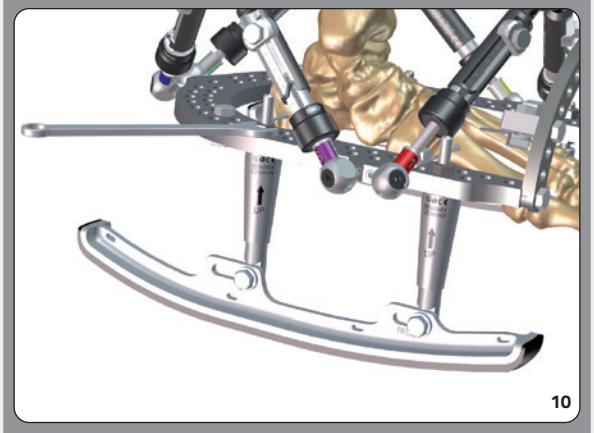
7. If longer threaded rods are needed, please remove the provided rods with the 1/8" Allen Wrench



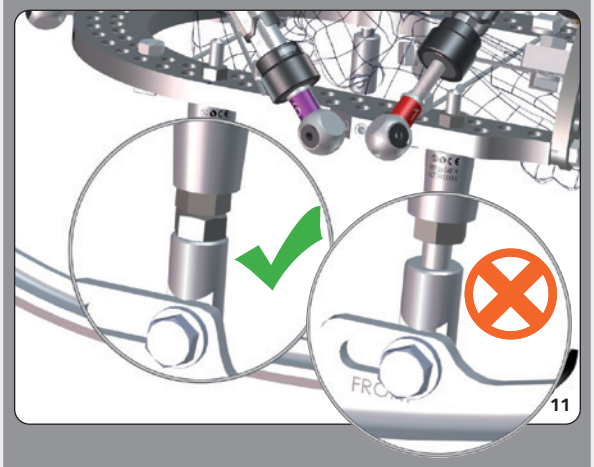
8. Exchange the rods with the threaded rods of the desired length



9. If threaded rods longer than 60mm are necessary, strengthen the construct with the Rocker Rail Extension Kits. Do not use threaded rods longer than 115mm. In case a greater extension is needed, consider adding an additional footplate

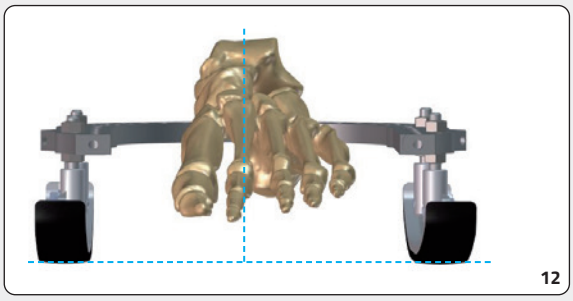


10.The larger side of the Extender must be in direct contact with the footplate

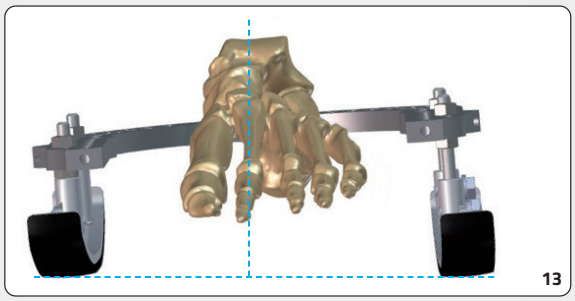


11.To adjust the distance between Footplate and Rocker Rail insert nuts and/or extended nuts between the Extender and the Rocker Rail. Do not allow any portion of bare rod

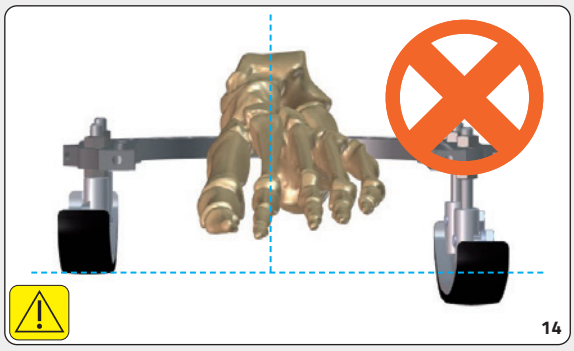
TrueLok RockerRail Final Check (Warnings & Precautions)



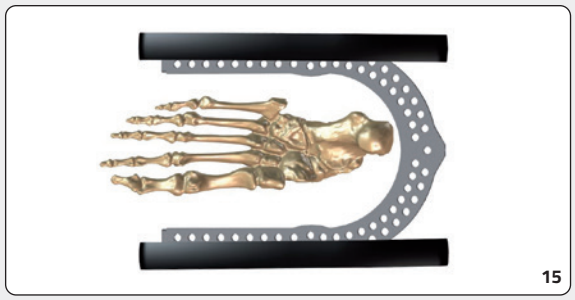
12.Make sure that the two rails are placed onto the Foot Plate to provide a balanced platform to the foot, keeping it in a neutral position



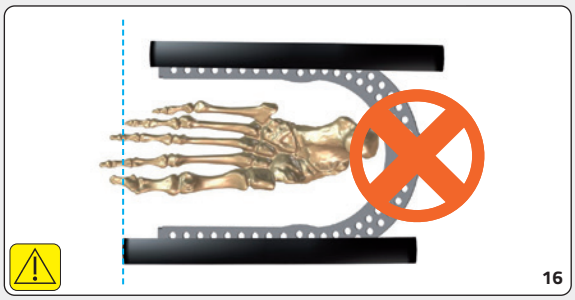
13.The rails can be placed unevenly relative to each other, but they should keep the foot in a neutral position



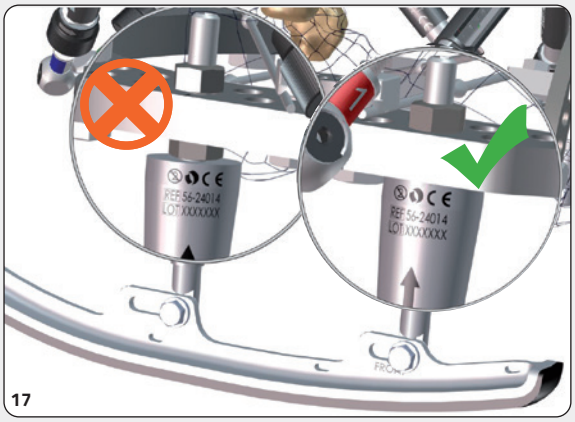
14.The rails should never be placed in a way to pronate or supinate the foot in static position



15.The front and the rear of the rails should always be in line with each other



16.The rails should never be placed offset to each other



17.Do not put nuts between the Footplate and the Extender

18.Use maximum one Extension Tube per threaded rod.

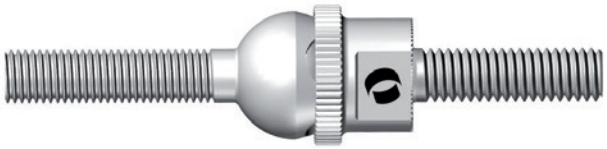
56-24000

56-24014

INSTRUMENT

Part#	Description	Qty.
52-1020	TL-HEX Driver 90°	1
		
54-1154	Wrench, Combo - 10mm	2
		
54-2226	Tubular Wrench	1
		

Spherical Joint
99-50-2310M (sterile, pack of 4)
The Spherical Joint is a versatile component that allows the surgeon to connect the dynamization module and external frame elements at virtually any angle up to 45°. The Spherical Joint can be locked in any position by tightening a standard nut and an external support against the joint housing.



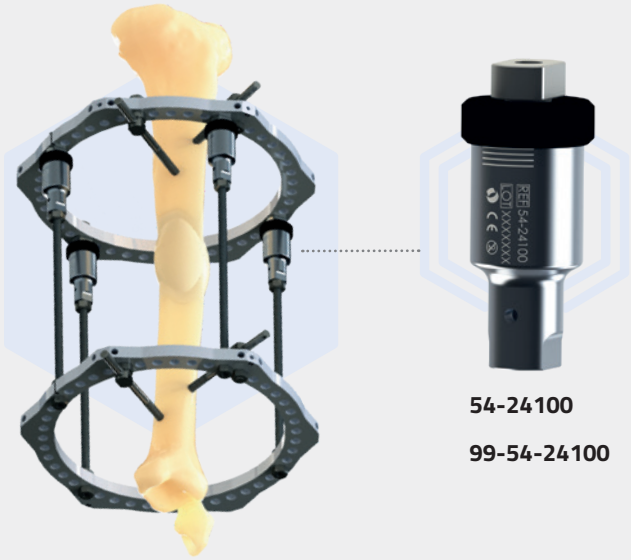
TL DYNAMIZATION MODULE

54-24100, 99-54-24100 (sterile)

Controlled Axial Dynamization
The TrueLok Dynamization Module can be used to dynamize an existing frame towards the end of treatment or at any stage where dynamization of the fracture callus or regenerate is required.

- Controlled micromotion amplitude up to 3mm
- No effect on ring separation distance no matter which micromotion setting from 0 to 3mm
- Compatible with all TrueLok and TL-HEX components
- Can be used with non-parallel ring orientation

For best results, the Dynamization Module must be orientated parallel to the bone anatomical axis.



54-24100

99-54-24100

WARNING: Do not use in applications that bridge an articulation.

PRECAUTION: The direction of dynamization is along the axis of the dynamization modules: hence, carefully define their orientation based on the intended direction of dynamization.

PRECAUTION: In order to dynamize correctly, the four dynamization modules must be placed on the same ring.

PRECAUTION: All the dynamizers must be fixed as parallel as possible to the bone axis.

PRECAUTION: The same level of dynamization must be set on all dynamization modules (code 55-24100 or 99-54-24100) using the reference lines.

DIRECT CONNECT WITH THREADED RODS

NON-PARALLEL WITH CONICAL WASHERS

NON-PARALLEL WITH UNIVERSAL HINGES

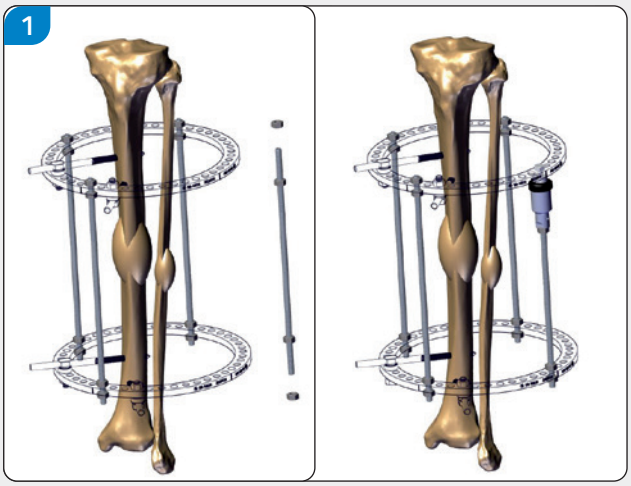
The amplitude of micromotion (dynamization) is achieved by turning the black knob. When the stroke is set to 0mm (Fig. A), the Dynamization Module produces no micromotion and, therefore, no dynamization is achieved. When the stroke is set to 3mm (Fig. B), up to 3mm of axial compression during dynamization can be achieved depending on patient body-weight loading.

N.B. The ring separation distance remains the same between Fig. A and Fig. B

Fig. A **Fig. B**

Part #	Description	Notes
54-24100	TL Dynamization Module	Out of the tray
99-54-24100	TL Dynamization Module, Sterile	Out of the tray

1



2

Instruments	Qty
Part#	
54-1154 	2
52-1018 	1

RADIOLUCENT DYNAMIZERS

99-50-2300M (sterile)

Controlled Axial Dynamization

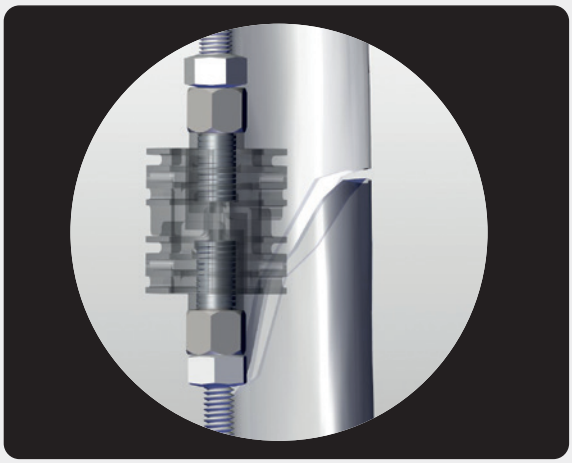
The Radiolucent Dynamizers are a sterile single-use component that can be used to dynamize an existing frame towards the end of treatment or at any stage where dynamization of the fracture callus or regenerate is required.

- It can be assembled through connection elements
- Controlled micromotion amplitude by 3mm
- Compatible with all TrueLok and TL-HEX components
- Axial movement cannot be changed during treatment
- Can be used with non-parallel ring orientation using spherical joint or hinges

WARNING: Do not use in applications that bridge an articulation.

PRECAUTION:
1. In order to dynamize correctly, the four radiolucent dynamizers must be placed on the same ring.
2. The direction of dynamization is along the axis of the radiolucent dynamizers: hence, carefully define their orientation based on the intended direction of dynamization.

PRECAUTION:
All the dynamizers must be fixed as parallel as possible to the bone axis.



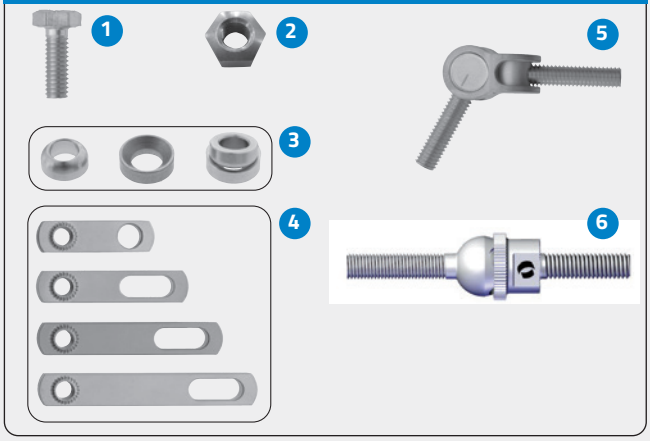
Radiolucent Dynamizer

Part #	Description	Notes
99-50-2300M	TL Radiolucent Dynamizer pack of 4	Sterile, 4 pieces per pack

CONNECTION ELEMENTS

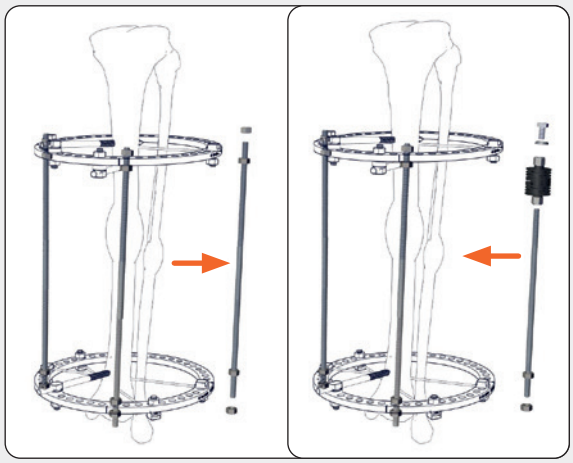
Part #		Description
54-1050 54-1050M 54-1010 54-1010M 54-1018	1	BOLTS
~~54~~ 50-1008 ~~54~~ 50-1008M	2	NUTS
54-1150 54-1150M	3	CONICAL WASHER
55-10340 55-11670 55-11671 55-11680	4	PLATES
55-1176	5	UNIVERSAL HINGE
99-50-2310M	6	SPHERICAL JOINT

CONNECTION ELEMENTS

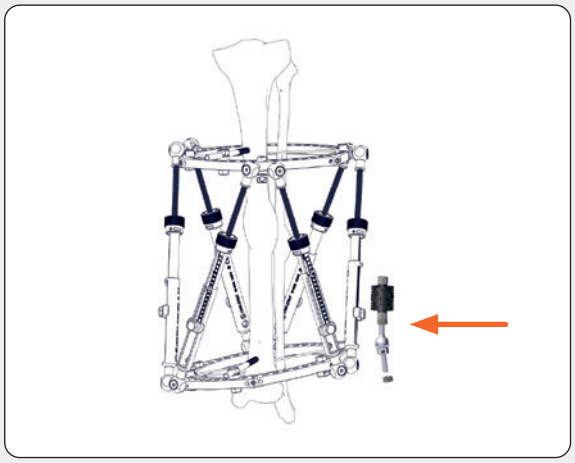


Instruments

Part #		Qty
54-1154		2
52-1018		1



In the case of a TrueLok frame, remove one connector at a time and replace it with a dynamizer structure.



In the case of a TL Hex frame, insert all dynamizer structures and remove one connector at a time.

The final dynamization position set up. The image show the use of connections elements including Spherical Joint and a plate since the rings are not parallel.

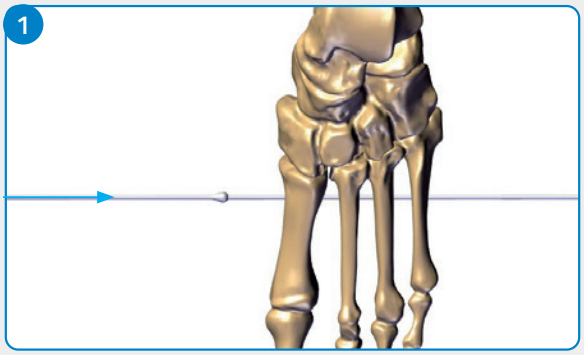
TRUELOK - FOREFOOT ARCH

56-14140 -
TRUELOK PLUS FOREFOOT REDUCTION ARCH 140MM

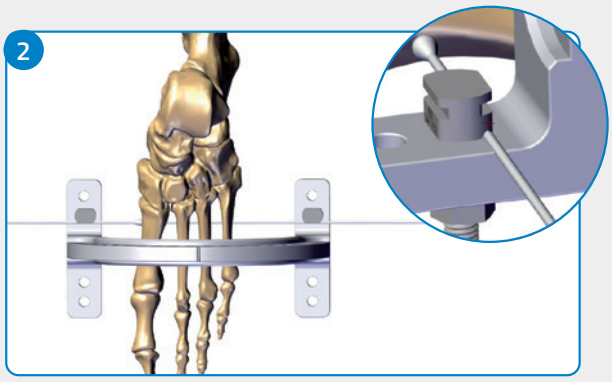
56-14160 -
TRUELOK PLUS FOREFOOT REDUCTION ARCH 160MM

- The TrueLok Forefoot Arch is compatible with TrueLok and TL-HEX™ frame
- Patient should be warned about hazards related to weight bearing, including failure of the frame
- For important medical information and maintenance consult Instructions for Use PQ TLK

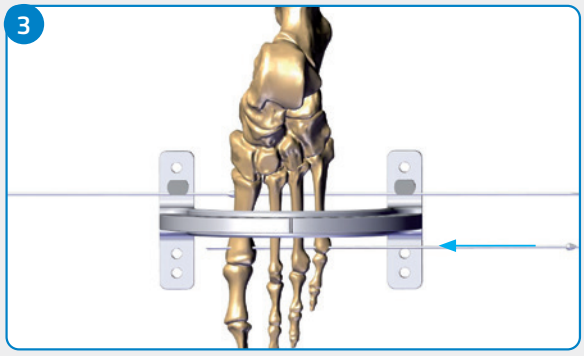
TrueLok Forefoot Arch application (Refer to pictures)



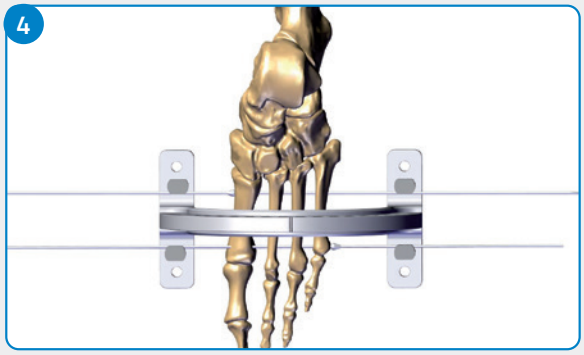
1. Insert the first wire with olive across the foot at the level of the proximal portion of the metatarsus



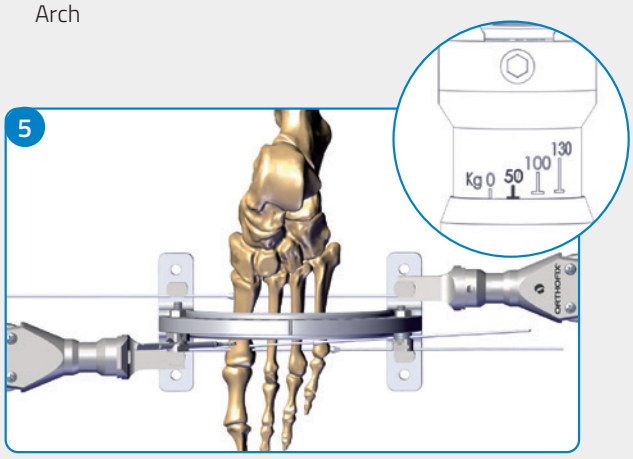
2. Link the wire to the stands of the Forefoot Arch



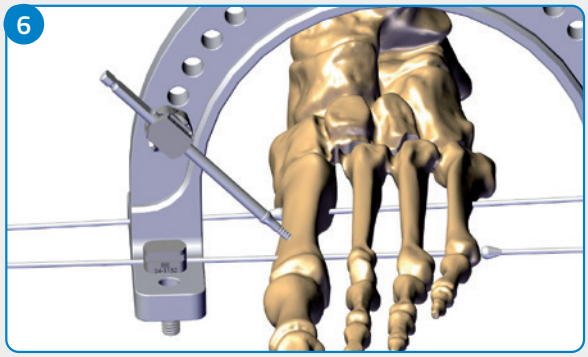
3. Using the Forefoot Arch as a template put the second wire with the olive on the opposite side of the foot



4. Link the second wire to the stands of the Forefoot Arch

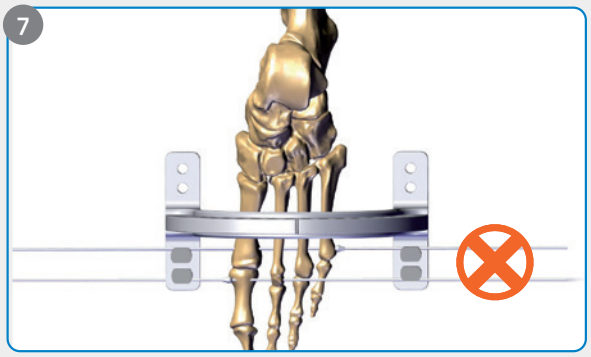


5. Tension the wires as appropriate according to bone stock quality

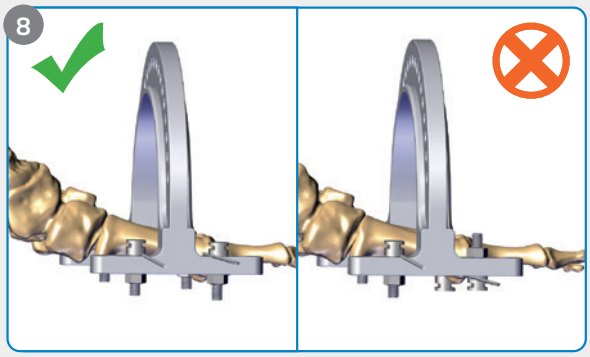


6. If needed, put additional wires or half pin across the foot

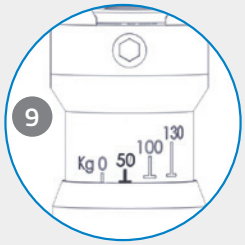
TRUELOK FOREFOOT ARCH APPLICATION - PRECAUTIONS (Refer to pictures)



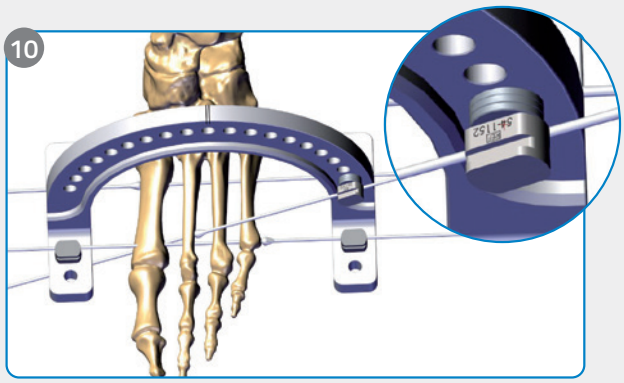
7. At least one wire must be inserted on either side of the Forefoot Arch



8. Wires must all be either positioned above or below the stands of the Forefoot Arch. Variable wire positioning above and below the stands must be avoided

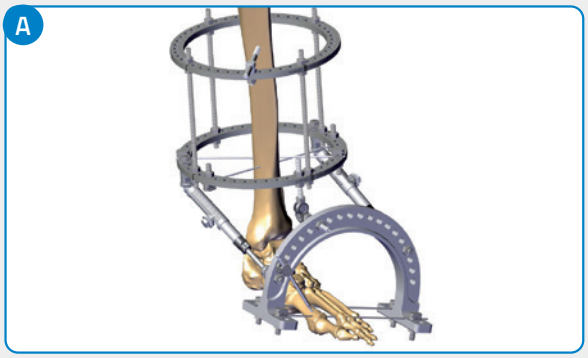


9. 50 Kgs for wire tensioning is recommended, paying attention that the olive on the wire does not go into the bone

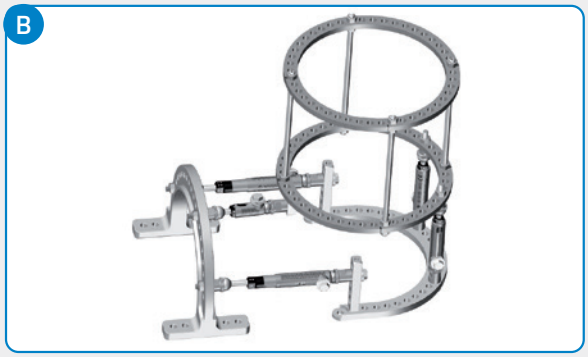


10. When attaching additional wires to the Forefoot Arch, washers must be used to avoid impingement on the arch lip and bending of the wire

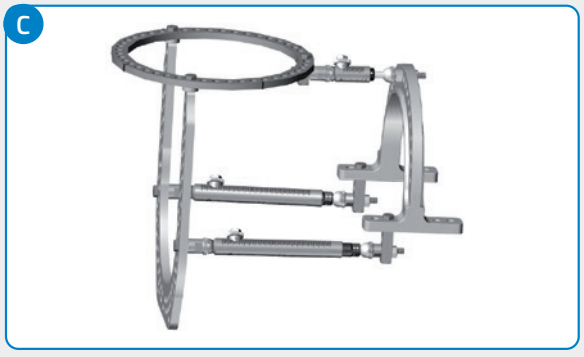
TrueLok Forefoot arch connection (Refer to pictures)



A. Optionally, the Forefoot Arch can be connected to TrueLok or TL-HEX frame



B. Alternative option to connect the dorsal aspect of the Forefoot Arch to a frame using struts

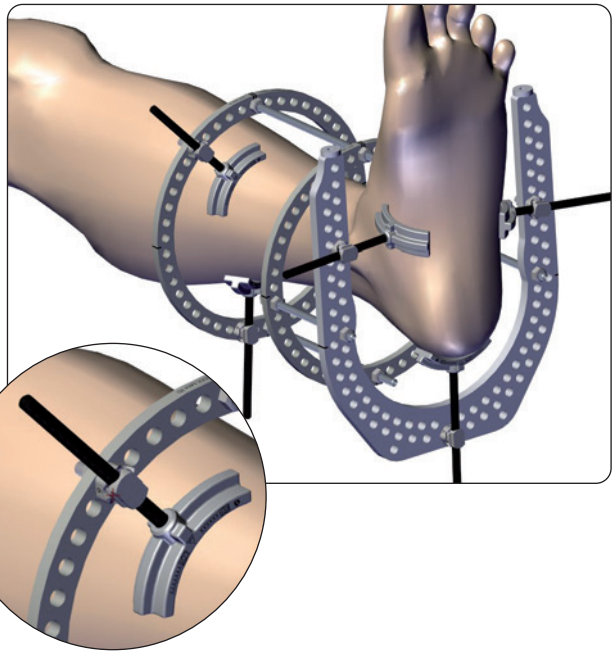


C. Alternative option to connect the dorsal aspect of the Forefoot Arch to a heel ring using struts

TrueLok FOOT ALIGNMENT SUPPORT
(99-56-24200M sterile, pack of 3)
Attach a half-pin bolt to the foot plate, slide the foot alignment support in the half-pin bolt and secure it by hand-tightening the bolt. Attach two additional foot alignment supports to the foot plate and if needed to the other rings as described above.

The Foot Alignment Support should be inserted through a half pin fixation bolt. Manually tighten a speed nut to fix the Foot Alignment Support in desired position. Finally, tighten the speed nut and the half pin fixation bolt using two 10mm wrenches.

At the end of the surgery, remove the Foot Alignment Support.



PRECAUTION: Ensure that the TL Foot Alignment Support that interfaces with the patient's skin is free from burrs or sharp edges.

PRECAUTION: Ensure that three TL Foot Alignment Supports are attached to one TL ring in order to achieve correct limb placement. The position of each Support shall be evaluated based on patient's case.

TRUELOK COMPONENTS

Ring Tray, TrueLok, Empty - 450500

A combination of any three layers can be combined to form a full rings tray.

450500-01 - LAYER 80-100 Can accommodate		
Part Number	**Description**	**Quantity**
56-10840	TL Plus Full Ring 80mm	4
56-11570	TL Plus Half Ring 80mm	2
56-12580	TL Plus Five Eighths Ring 100mm	1
56-10860	TL Plus Full Ring 100mm	4
56-11580	TL Plus Half Ring 100mm	2
56-13580	TL+ Footplate 100mm	1

450500-02 - LAYER 120 Can accommodate		
Part Number	**Description**	**Quantity**
56-10890	TL Plus Full Ring 120mm	4
56-11590	TL Plus Half Ring 120mm	2
56-12590	TL Plus Five Eighths Ring 120mm	1
56-13590	TL Plus Footplate 120mm	1

450500-03 - LAYER 130 Can accommodate		
Part Number	**Description**	**Quantity**
56-10900	TL Plus Full Ring 130mm	4
56-11600	TL Plus Half Ring 130mm	2
56-12600	TL Plus Five Eighths Ring 130mm	1
56-13600	TL+ Footplate 130mm	1

450500-04 - LAYER 140 Can accommodate		
Part Number	**Description**	**Quantity**
56-10910	TL Plus Full Ring, 140mm	4
56-11610	TL Plus Half Ring 140mm	2
56-12610	TL Plus Five Eighths Ring 140mm	1
56-13610	TL+ Footplate 140mm	1

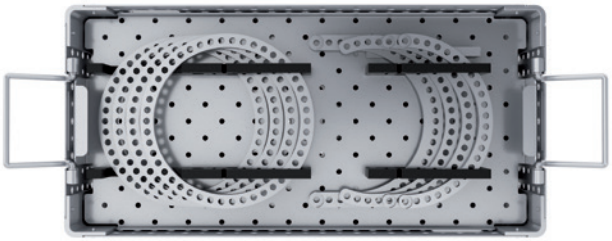
450500-05 - LAYER 150 Can accommodate		
Part Number	**Description**	**Quantity**
56-12620	TL Plus Five Eighths Ring 150mm	1
56-13620	TL Plus Footplate 150mm	1
56-10920	TL Plus Full Ring, 150mm	4
56-11620	TL Plus Half Ring 150mm	2

450500-06 - LAYER 160 Can accommodate		
Part Number	**Description**	**Quantity**
56-10930	TL Plus Full Ring 160mm	4
56-11630	TL Plus Half Ring 160mm	2
56-12630	TL Plus Five Eighths Ring 160mm	1
56-13630	TL+ Footplate 160mm	1

450500-07 - LAYER 170 Can accommodate		
Part Number	**Description**	**Quantity**
56-10940	TL Plus Full Ring, 170mm	4
56-11640	TL Plus Half Ring 170mm	2
56-12640	TL Plus Five Eighths Ring 170mm	1
56-13640	TL+ Footplate 170mm	1

450500-08 - LAYER 180 Can accommodate		
Part Number	**Description**	**Quantity**
56-10950	TL Plus Full Ring 180mm	4
56-11650	TL Plus Half Ring 180mm	2
56-12650	TL Plus Five Eighths Ring 180mm	1
56-13650	TL+ Footplate 180mm	1

450500-09 - LAYER 200 Can accommodate		
Part Number	**Description**	**Quantity**
56-10960	TL Plus Full Ring, 200mm	4
56-11660	TL Plus Half Ring 200mm	2
56-12660	TL Plus Five Eighths Ring 200mm	1
56-13660	TL+ Footplate 200mm	1

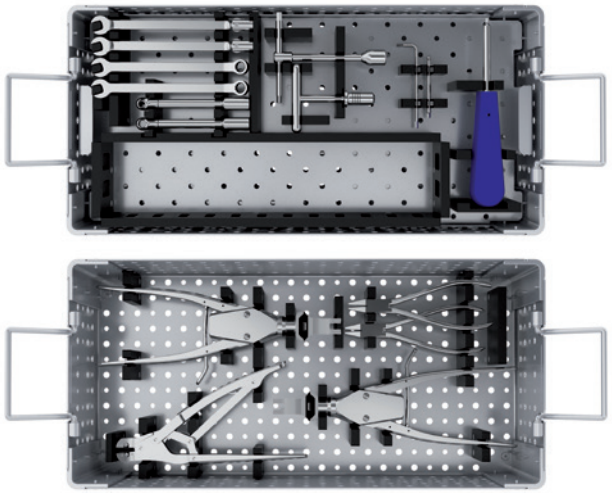


450500

Instrument Tray, TrueLok, 450501

Can accommodate

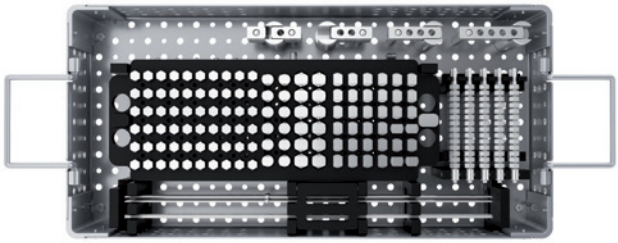
Part Number	Description	Quantity
W1003	Wire Cutter	1
54-1139	TL Plus Wire Tensioner with Tip	2
54-2227	Needle Nose Pliers, Stainless Steel	2
52-1018	TL, 1/8' Hex Driver	1
52-1020	TL, Hex Driver, 90-Degree, 1/8"	1
54-1154	TL,Wrench, Combo, 10mm	2
54-1155	TL,Wrench, Hinged Combo, 10mm	2
54-2226	TL, 90 Degree Tubular Wrench	2
91150	Universal T-Wrench	1
52-10210	TL+ AO 1/8' Hex Power Driver Attachment	1
54-2229	T-Wrench With AO Connection	1



450501

Fixation Elements Tray, TrueLok, 450503-
Can accommodate

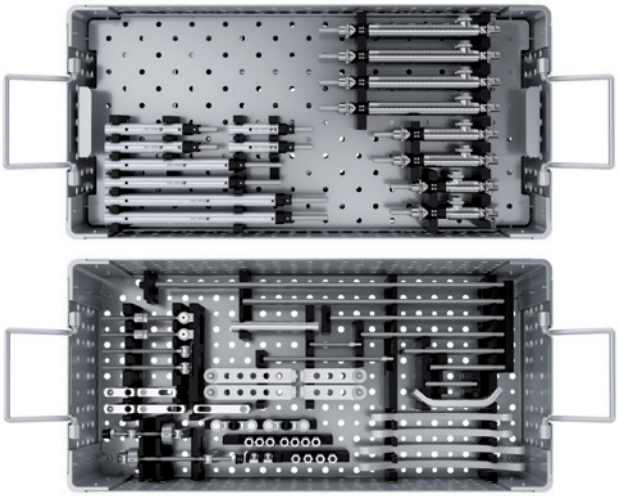
Part Number	Description	Quantity
50-1008	TL, Nut, Stainless Steel, 10mm	120
50-13010	TL+ Metal Distraction / Compression Nut	16
50-13020	TL+ Extended Nut M6 X 1	10
54-1010	TL, Bolt, 16mm	24
54-1018	TL, Bolt, 20mm	12
54-10.50	TL, Bolt, 12mm	24
54-1064	TL Washer, Slotted	8
54-1133	Stopper, Red Rubber, Wire	27
54-1136	Stopper, Gray Rubber, Half Pin	9
54-11530	TL+ Universal Half Pin Fixation Bolt 4mm - 6mm	12
54-11600	TL+ One Hole Post	4
54-11610	TL+ Two Hole Post	4
54-11620	TL+ Three Hole Post	4
54-11630	TL+ Four Hole Post	2
54-11640	TL+ Five Hole Post	2
54-1215	TL, Wire, W/Stopper, 1.8mm x 400mm	12
54-1216	TL, Wire, Bayonet, 1.8mm x 400mm	12
54-1134	TL, Applicator Rubber Stopper	2
54-1142	Stainless Steel Washer, 2mm Thick	12
54-1150	TL, Washer, Conical Pair	16
54-1152	TL, Bolt, Wire Fixation, Universal	24
54-1151	TL, Short Bolt, Wire Fixation, Universal	12
54-2235	M6 X 1 Hex, Speednut, Truelok System	16
54-11540	TL 8mm Half Pin Bolt	12



450503

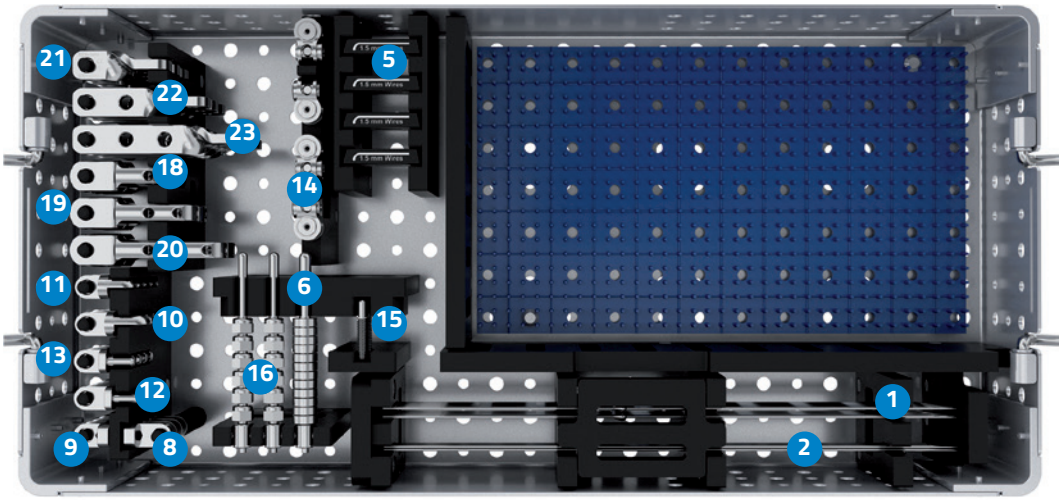
Hinges and Distractors Tray, TrueLok, 450504
Can accommodate

Part Number	Description	Quantity
51-10300	TL+ Threaded Hinge Rod, 60mm	4
51-10430	TL+ Cannulated Inline Hinge Assembly	2
51-10440	TL+ Outboard Hinge Assembly	2
51-10460	TL+ Angular Distractor Assembly, 100mm	1
51-10470	TL+ Angular Distractor Assembly, 150mm	1
51-10550	TL+ Threaded Hinge Rod 150mm	4
55-10060	115mm Threaded Rod	8
55-10070	165mm Threaded Rod	8
55-10340	TL Plus 20mm Plate	8
55-10530	85mm Threaded Rod	8
55-10.99	TL, Oblique Support	4
55-11670	TL+ 30mm Plate	4
55-11671	TL+ 40mm Plate	4
55-11680	TL+ 50mm Plate	4
55-11720	60mm Threaded Rod	8
54-11650	TL+ Hex Standoff	4
54-11660	TL Plus Hex Standoff 30mm	8
55-1176	TL, Hinge, Universal	4
55-11730	TL+ Threaded Hex End Rod 200mm	4
55-11740	TL+ Threaded Hex End Rod 300mm	4
55-11750	TL+ Threaded Hex End Rod 400mm	4
51-10220	TL+, 100mm Telescopic Hinge Extender	2
56-14580	TL+ Foot Plate Extension 3 Hole	4
56-14590	TL+ Foot Plate Extension 5 Hole	4
55-10760	TL Plus 90mm Arch	2
55-10800	TL Plus 120mm Arch	2
51-10462	Bracket Assembly, Swivel Stud, Angular Distractor, Truelok	2
50-10140	TL+ Telescopic Linear Distractor 100mm	4
50-10150	TL+ Telescopic Linear Distractor 150mm	4
50-10160	TL+ Telescopic Linear Distractor 200mm	4
50-11010	TL+ Telescopic Linear Distractor 70mm	4
50-10170	TrueLok Plus Short Quick Adjust Strut	4
50-10180	TrueLok Plus Medium Quick Adjust Strut	4
50-10190	TrueLok Plus Long Quick Adjust Strut	8



450504

(TL+) FOOT & ANKLE KIT



450502

(TL+) Foot & Ankle Kit - 450502

Code		Description	Q.ty
54-1217	1	TL Plus Bayonet Wire with olive L300mm Ø1.5mm	12
54-1218	2	TL Plus Bayonet Wire without olive L300mm Ø1.5mm	12
54-1213	3	TL Plus X-Wire with olive L300mm Ø1.5mm	on demand
54-1214	4	TL Plus X-Wire without olive L300mm Ø1.5mm	on demand
54-1141	5	TL Plus Tension Limiter	4
54-1143	6	TL Plus Washer 4mm Thick	12
54-1143M	7	TL Plus Washer 4mm Thick pack of 10	
56-24050	8	TL Plus Hinge Female High Profile	12
56-24051	9	TL Plus Hinge Female Low Profile	4
56-24060	10	TL Plus 90° Hinge High Profile	4
56-24061	11	TL Plus 90° Hinge Low Profile	4
56-24070	12	TL Plus Hinge Male High Profile	4
56-24071	13	TL Plus Hinge Male Low Profile	4
51-10420	14	TL Plus non Lockable Universal Joint	4
51-10290	15	TL Plus Threaded Hinge Rod L30mm	4
50-1010	16	TL Plus Nylon Insert Nut	12
50-1010M	17	TL Plus Nylon Insert Nut pack of 10	
54-11670	18	TL Plus Twisted Plate 2 Holes	3
54-11680	19	TL Plus Twisted Plate 3 Holes	3
54-11690	20	TL Plus Twisted Plate 4 Holes	3
81641	21	TL Plus 90° Plate 1 Hole	2
81642	22	TL Plus 90° Plate 2 Holes	2
81643	23	TL Plus 90° Plate 3 Holes	2
450502	24	TL Plus Foot&Ankle Kit Tray Empty	
450502-01	25	TL Plus Foot&Ankle Kit Lid	
450502-02	26	TL Plus Foot&Ankle Kit Base	
450502C	27	TL Plus Foot&Ankle Kit Tray Complete	

Material out of the tray (Sterile)

Code	Description
99-54-1650	K-Wire, 450mm, No Olive TL-HEX Sterile
99-54-1750	K-Wire, 550mm, Olive TL-HEX Sterile

Components available also in sterile packaging

Code	Description
99-50-10100	ULTRA SHORT STRUT TL-HEX - 45MM-101MM STERILE
99-50-10200	SHORT STRUT TL-HEX - 92MM-122MM STERILE
99-50-10300	MEDIUM STRUT TL-HEX - 114MM-184MM STERILE
99-50-10400	LONG STRUT TL-HEX - 158MM-318MM STERILE
99-50-10170	TRUE LOK PLUS SHORT QUICK ADJUST STRUT STERILE
99-50-10180	TRUE LOK PLUS MEDIUM QUICK ADJUST STRUT STERILE
99-50-10190	TRUE LOK PLUS LONG QUICK ADJUST STRUT STERILE
99-56-20000	FULL RING, 140MM, TL-HEX STERILE
99-56-20020	FULL RING, 160MM, TL-HEX STERILE
99-56-20040	FULL RING, 180MM, TL-HEX STERILE
99-56-20060	FULL RING, 200MM, TL-HEX STERILE
99-56-20200	FULL RING, 120MM, TL-HEX STERILE
99-56-20320	FULL RING, 100MM, TL-HEX STERILE
99-56-21200	MODULAR 5/8 RING, 120MM, TL-HEX STERILE
99-56-21320	MODULAR 5/8 RING, 100MM, TL-HEX STERILE
99-56-21400	MODULAR 5/8 RING, 140MM, TL-HEX STERILE
99-56-21420	MODULAR 5/8 RING, 160MM, TL-HEX STERILE
99-56-21440	MODULAR 5/8 RING, 180MM, TL-HEX STERILE
99-56-21460	MODULAR 5/8 RING, 200MM, TL-HEX STERILE
99-56-23000	3/8 RING, 100MM, TL-HEX STERILE
99-56-23020	3/8 RING, 120MM, TL-HEX STERILE
99-56-23040	3/8 RING, 140MM, TL-HEX STERILE
99-56-23060	3/8 RING, 160MM, TL-HEX STERILE
99-56-23080	3/8 RING, 180MM, TL-HEX STERILE
99-56-23100	3/8 RING, 200MM, TL-HEX STERILE
99-56-24040	TL HEX EMERGENCY TAB KIT STERILE
99-54-11230	TL+ HALF PIN QUICK CONNECT 4MM X 180MM STERILE
99-54-11240	TL+ HALF PIN QUICK CONNECT 5MM X 180MM STERILE
99-54-11250	TL+ HALF PIN QUICK CONNECT 6MM X 180MM STERILE
99-50-10215	STRUT NUMBER CLIP KIT, TL-HEX (6 PCS) STERILE
99-50-10214	STRUT DIRECTION CLIP KIT, TL-HEX (6 PCS) STERILE
99-50-10140	TL+ TELESCOPIC LINEAR DISTRACTOR 100MM STERILE
99-50-10150	TL+ TELESCOPIC LINEAR DISTRACTOR 150MM STERILE
99-50-10160	TL+ TELESCOPIC LINEAR DISTRACTOR 200MM STERILE
99-50-11010	TL+ TELESCOPIC LINEAR DISTRACTOR 70MM STERILE
99-54-1215	TL, Wire, W/Stopper, 1.8mm x 400mm Sterile
99-54-1216	TL, Wire, Bayonet, 1.8mm x 400mm Sterile

Components available also in sterile packaging

Code	Description
99-50-2310M	TRUELOK SPHERICAL JOINT PACK OF 4 STERILE
99-54-1217	TL PLUS BAYONET WIRE WITH OLIVE L300MM D1.5MM STERILE
99-54-1218	TL PLUS BAYONET WIRE WITHOUT OLIVE L300MM D1.5MM STERILE
99-54-24100	TL DYNAMIZATION MODULE STERILE
99-56-10840	TL PLUS FULL RING 80MM STERILE
99-56-10860	TL PLUS FULL RING 100MM STERILE
99-56-10890	TL PLUS FULL RING, 120MM STERILE
99-56-10910	TL PLUS FULL RING, 140MM STERILE
99-56-10930	TL PLUS FULL RING, 160MM STERILE
99-56-10950	TL PLUS FULL RING, 180MM STERILE
99-56-10960	TL PLUS FULL RING, 200MM STERILE
99-56-10970	TL PLUS FULL RING, 220MM STERILE
99-56-10980	TL PLUS FULL RING, 240MM STERILE
99-56-11570	TL PLUS HALF RING 80MM STERILE
99-56-11580	TL PLUS HALF RING 100MM STERILE
99-56-11590	TL PLUS HALF RING 120MM STERILE
99-56-11610	TL PLUS HALF RING 140MM STERILE
99-56-11630	TL PLUS HALF RING 160MM STERILE
99-56-11650	TL PLUS HALF RING 180MM STERILE
99-56-11660	TL PLUS HALF RING 200MM STERILE
99-56-11670	TL PLUS HALF RING 220MM STERILE
99-56-11680	TL PLUS HALF RING 240MM STERILE
99-56-12580	TL PLUS FIVE EIGHTHS RING 100MM STERILE
99-56-12590	TL PLUS FIVE EIGHTHS RING 120MM STERILE
99-56-12610	TL PLUS FIVE EIGHTHS RING 140MM STERILE
99-56-12620	TL PLUS FIVE EIGHTHS RING 150MM STERILE
99-56-12630	TL PLUS FIVE EIGHTHS RING 160MM STERILE
99-56-12650	TL PLUS FIVE EIGHTHS RING 180MM STERILE
99-56-12660	TL PLUS FIVE EIGHTHS RING 200MM STERILE
99-56-13580	TL+ FOOTPLATE 100MM STERILE
99-56-13590	TL PLUS FOOTPLATE 120MM STERILE
99-56-13610	TL+ FOOTPLATE 140MM STERILE
99-56-13625	150 MM DOUBLE ROW FOOT PLATE STERILE
99-56-13630	TL+ FOOTPLATE 160MM STERILE
99-56-13635	160 MM DOUBLE ROW FOOT PLATE STERILE
99-56-13650	TL+ FOOTPLATE 180MM STERILE
99-56-13655	180 MM DOUBLE ROW FOOT PLATE STERILE
99-56-13660	TL+ FOOTPLATE 200MM STERILE
99-56-13665	200 MM DOUBLE ROW FOOT PLATE STERILE
99-56-24200M	TRUELOK FOOT LEG ALIGNMENT SUPPORT PACK OF 3 STERILE

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Electronic Instructions for use available at the website http://ifu.orthofix.it

Electronic Instructions for use - Minimum requirements for consultation:
- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):
tel +39 045 6719301, fax +39 045 6719370,
e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

Manufactured by:
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo
(Verona), Italy
Telephone +39 045 6719000,
Fax +39 045 6719380
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