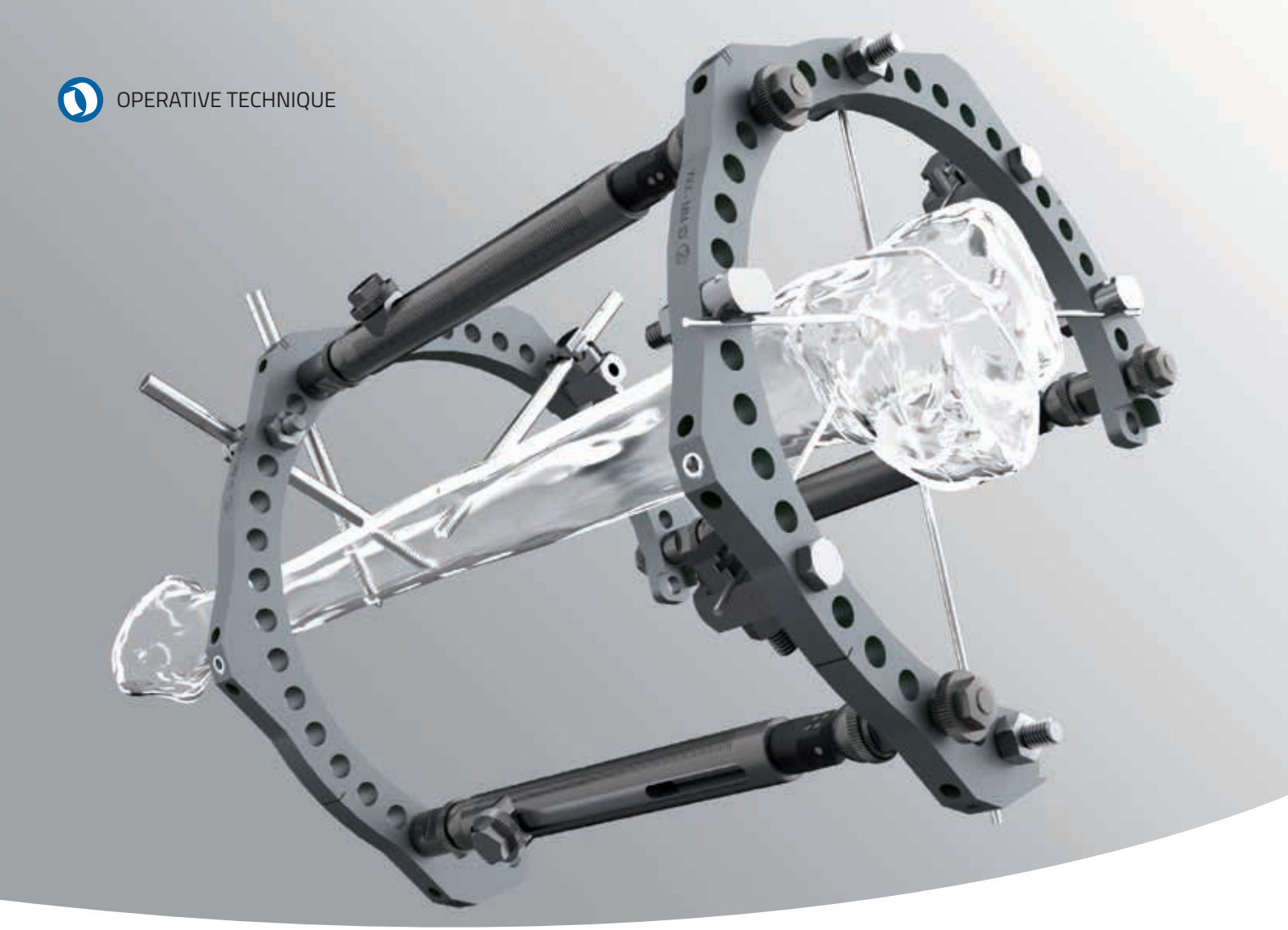
OPERATIVE TECHNIQUE



TL-HEX TRAUMA

ORTHOFIX®

CONTENTS

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 see the Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

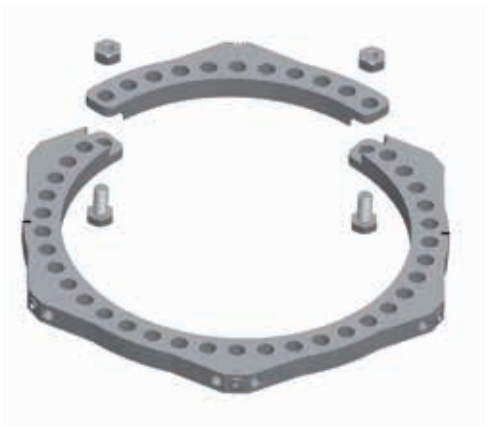
INTRODUCTION

Presented below are some examples of the basic TL-HEX frame assemblies for reduction and stabilization of tibial and femural fractures.
Indications for the TL-HEX trauma frame include stabilization of closed and open fractures and situations when fracture reduction can be achieved intraoperatively.

TL-HEX rings can be applied in any desired position, using complete or 5/8 rings. If two 5/8 rings are used the openings should be in line, allowing the surgeons to maintain traction on the patient's limb. The basic principles of aligning a ring on the limb perpendicular to its long axis should be followed. Either wires or half pins (or a combination of both) can be used to secure thering to the limb depending on surgeon preferences and space availability.

TL-HEX TrueLok Hexapod System®
EXTERNAL SUPPORTS

Circular external components
TL-HEX external supports are lightweight, partially radiolucent, 9.5mm thick and made of anodized high-strength aircraft grade aluminum. They are offered in 10 diameters (from 100mm to 300mm). Rings may be used either 'full' (by combining a 5/8 and a 3/8 ring) or 'partial' (using only the 5/8 component).
This modularity provides increased options for access and stiffness of the construct, all available in the same tray.



TRUELOK ASSEMBLY ELEMENTS

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

Bolts
Length: 12mm, 16mm, 20mm.

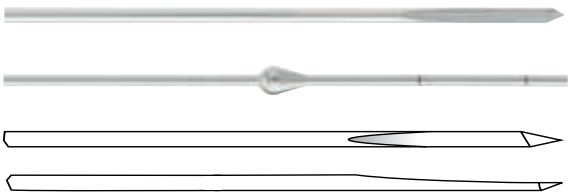
Nuts

Spacing Washer
2mm thick.

M6 X 1 Hex, Speednut

Extended Nut
Lenght 10mm Hex Head

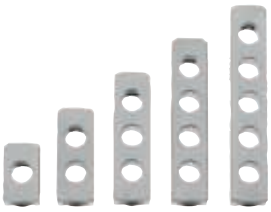
Wires
1.8mm diameter wires are available in two types: smooth and wires with olive. The latter provide a stop at the bone interface. Both wire styles have a bayonet-shaped, eccentric tip, which efficiently drills through both cortical and cancellous bone without generating excessive heat.



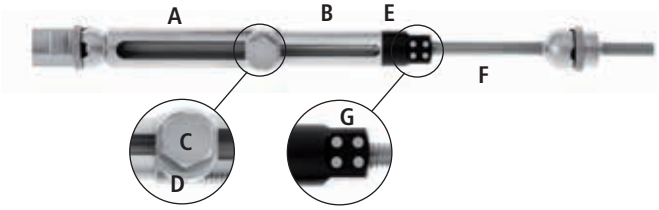
Universal Wire Fixation Bolt
The TrueLok universal wire fixation bolt head is slotted and the bolt neck is cannulated to accept a 1.8mm or 1.5mm wire. An additional design feature is the horizontal grooves on the slot and base of the head which enhance the gripping force on the wire.

TrueLok 8mm Half Pin Fixation Bolt
The TrueLok 8mm half pin fixation bolt 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 also the insertion of a soft tissue protector. The specific design of the bolt minimizes the tension on the pins during tightening.

Posts
Sizes: from 1 hole to 5 holes.
The posts have a standard female threaded base, allowing them to be secured to an external support by a 16mm bolt. The serrations on the base prevent undesirable rotation after tightening.



Quick Adjust Struts
Quick Adjust Struts are available in 3 sizes (short, medium and long). They have a lockable universal hinge on both ends which allows acute angular and rotational corrections. 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.

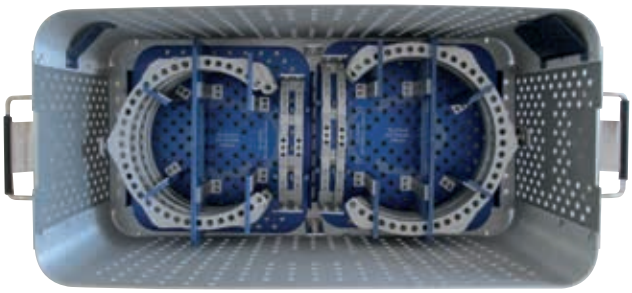


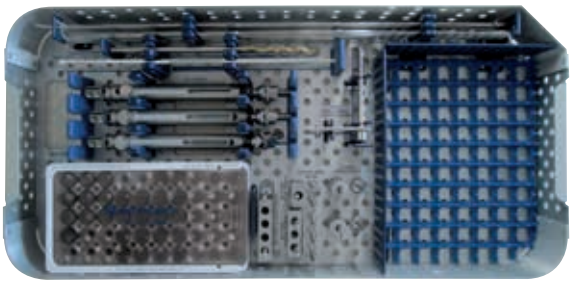
The inner tube is attached to a square-sided plastic bushing **(E)**. The plastic bushing mates with the threaded rod **(F)** in a manner such that the rod moves relative to the aluminum tube when the plastic bushing is rotated, thus allowing for micro-compression or distraction. The four sided bushing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

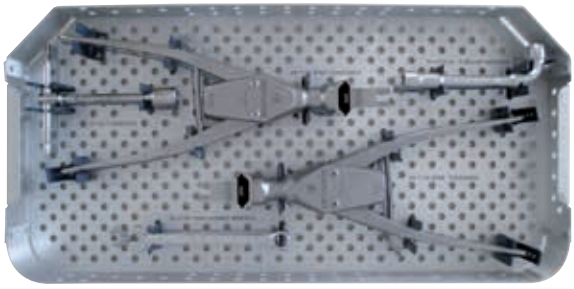
EQUIPMENT SUGGESTED

Trauma Tray, TL-HEX, code 30110129 (empty)

Part Number	Description	Q.ty
30110129C	Trauma Tray, TL-HEX, complete	1
56-23060	3/8 Ring, 160mm, TL-HEX	2
56-21420	Modular 5/8 Ring, 160mm, TL-HEX	4
56-23080	3/8 Ring, 180mm, TL-HEX	2
56-21440	Modular 5/8 Ring, 180mm, TL-HEX	4
50-10190	True Lok Plus Long Quick Adjust Strut	6
92050	Transfixing Pin, Thread L 50mm Shaft Ø 4mm, Thread Ø 5mm	1
54-1215	TL, Wire, W/Stopper, 1.8mm x 400mm	6
54-1216	TL, Wire, Bayonet, 1.8mm x 400mm	2
54-11600	TL+ One Hole Post	3
54-11620	TL+ Three Hole Post	3
54-11640	TL+ Five Hole Post	3
54-11540	TL 8mm Half Pin Bolt	15
OPTIONAL 54-11530	TL+ Universal Half Pin Fixation Bolt 4mm - 6mm	15
54-1152	TL, Bolt, Wire Fixation, Universal	20
54-1010	TL, Bolt, 16mm	15
50-1008	TL, Nut, Stainless Steel, 10mm	30
54-2235	M6 X 1 HEX, Speednut, TrueLok System	12
17976	Short Graduated Drill Bit 4.8X180mm	1
or 1100101	Drill Bit, 4.8mm x 180mm Tin Coated - Quick Connect	1
11.105	Drill Guide Ø 4.8mm Length 80mm	1
91150	Universal T-Wrench	1
54-2226	TL, 90 Degree Tubular Wrench	1
54-1154	TL, Wrench, Combo, 10mm	1
54-1139	TL PLUS Wire Tensioner With Tip	2







Out of the tray

5/8 Rings

Part Number	Description	Q.ty
56-21320	5/8 Modular Ring 100mm TL-HEX	1
56-21200	5/8 Modular Ring 120mm TL-HEX	1
56-21400	5/8 Modular Ring 140mm TL-HEX	1
56-21420	5/8 Modular Ring 160mm TL-HEX	1
56-21440	5/8 Modular Ring 180mm TL-HEX	1
56-21460	5/8 Modular Ring 200mm TL-HEX	1
99-56-21480	5/8 Modular Ring 220mm TL-HEX (Sterile)	1
99-56-21220	5/8 Modular Ring 240mm TL-HEX (Sterile)	1
99-56-21240	5/8 Modular Ring 280mm TL-HEX (Sterile)	1
99-56-21340	5/8 Modular Ring 300mm TL-HEX (Sterile)	1

3/8 Rings

Part Number	Description	Q.ty
56-23000	3/8 Ring 100mm TL-HEX	1
56-23020	3/8 Ring 120mm TL-HEX	1
56-23040	3/8 Ring 140mm TL-HEX	1
56-23060	3/8 Ring 160mm TL-HEX	1
56-23080	3/8 Ring 180mm TL-HEX	1
56-23100	3/8 Ring 200mm TL-HEX	1
99-56-23120	3/8 Ring 220mm TL-HEX (Sterile)	1
99-56-23140	3/8 Ring 240mm TL-HEX (Sterile)	1
99-56-23160	3/8 Ring 280mm TL-HEX (Sterile)	1
99-56-23180	3/8 Ring 300mm TL-HEX (Sterile)	1

NOTE: all Rings are also available packaged sterile. They can be ordered using the above code numbers preceded by 99- (e.g. 99-56-21460)

Out of the tray

Instruments

Part Number	Description	Q.ty
20116735	TL Short Tensioner Tip	2
20116736	Extended Tensioner Tip Assembly	2
20116731	TrueLok System Retaining Tensioner Tip	2
54-1154	TL, Wrench, Combo, 10mm	1
52-1020	TL, Hex Driver, 90-Degree, 1/8"	1
54-11600	TL+ One Hole Post	1
54-11610	TL+ Two Hole Post	2
11103	Screw Guide, length 100mm	3
1100201	Drill Bit Ø 4.8mm length 240mm	1
11004	Trocar	1
W1003	Wire Cutter	1
54-11560	8mm Bolt Wrench	1
54-2233	TrueLok Plus Speed Bolt thread L16mm	1
99-54-2233	TrueLok Plus Speed Bolt thread L16mm Sterile	1
50-13020	Extended Nut - Lenght 10mm Hex Head	3

Bone Screws (Sterile)

Part Number	Description
99-911530*	XCaliber Bone Screw L150/30mm Thread Ø 6.0-5.6mm
99-911540*	XCaliber Bone Screw L150/40mm Thread Ø 6.0-5.6mm
99-911550*	XCaliber Bone Screw L150/50mm Thread Ø 6.0-5.6mm

* HA half pins also available

Quick Adjust Struts

Part Number	Description
50-10170	Truelok Plus Short Quick Adjust Strut
50-10180	Truelok Plus Medium Quick Adjust Strut
50-10190	Truelok Plus Long Quick Adjust Strut

NOTE: 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)

TL-HEX TRAUMA SURGICAL PROCEDURE

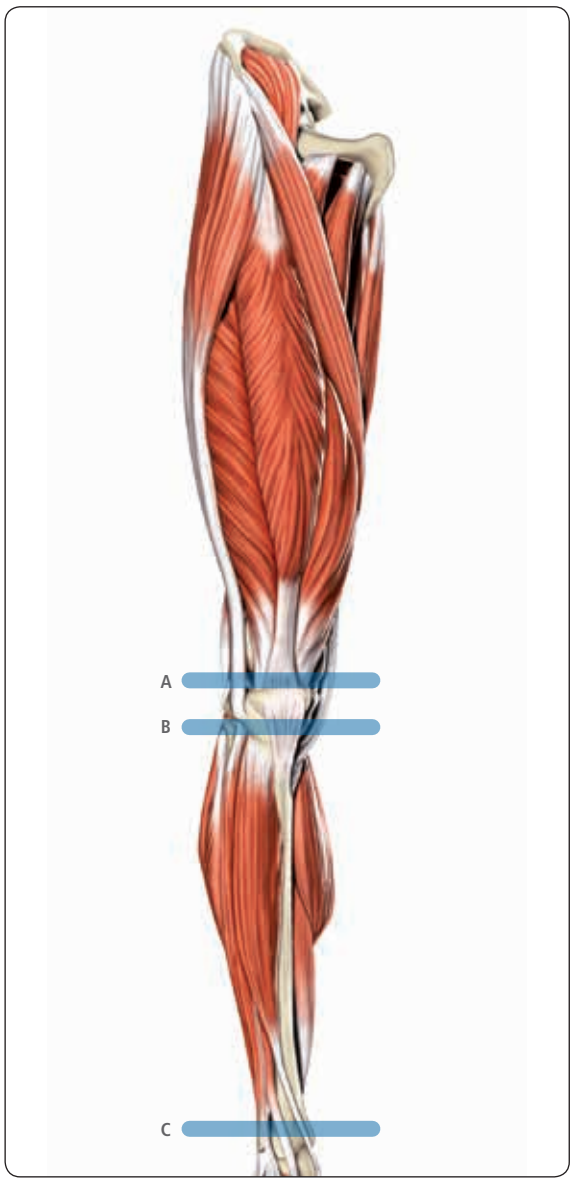
TL-HEX ring application

SAFE CORRIDORS

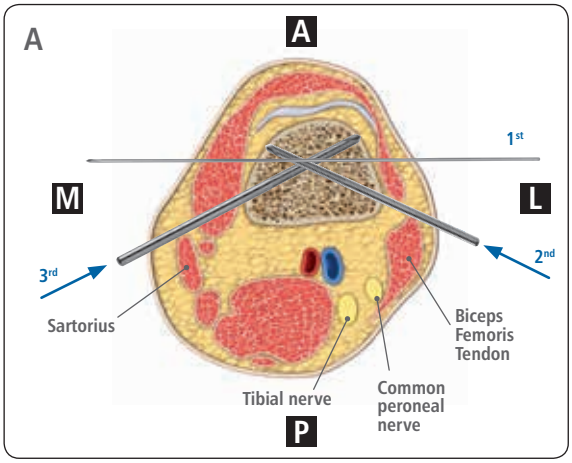
In figures A, B and C safe corridors for the insertion of the fixation elements are represented.

Distal Femur

Wire and screws fixation in the distal femur is challenging due to the important periarticular structures present. Furthermore, narrow wire crossing angles produce instability in the sagittal plane. Correct wire and screws insertion is therefore crucial.

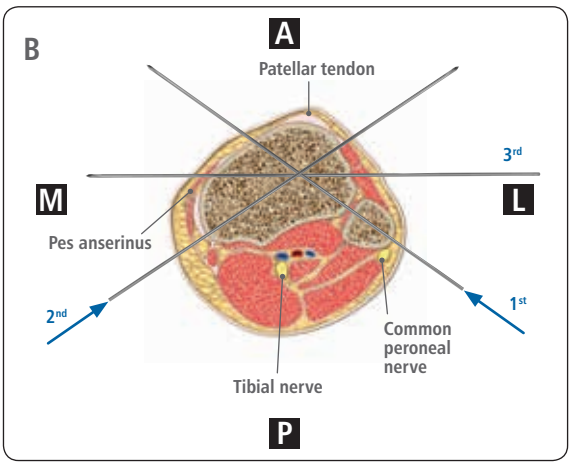


Firstly insert a wire from lateral to medial. Then insert two screws: one screw from postero-lateral to anteromedial, anterior to the Biceps Femoris Tendon, and one screw from postero-medial to anterolateral, anterior to the Sartorius. Wire and screws should be inserted with the knee flexed.



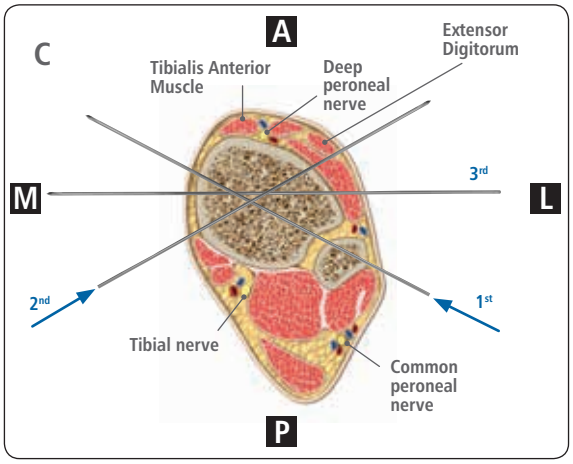
Proximal tibia

When inserting wires in the proximal tibia, the head of the fibula is an important landmark, since the Common Peroneal Nerve passes posterior to it. Care should be taken to avoid damage to this nerve and to the joint capsule. The first wire should pass from postero-lateral to antero-medial between the patellar tendon and pes anserinus. The crossing wire should be inserted at the widest angle neurovascular structures will permit from postero-medial to antero-lateral. The third wire should be inserted from lateral to medial.



Distal tibia

The most distal wire should be inserted first, approximately 1cm proximal to the articular surface of the tibia so that the more proximal wire remains close to, or immediately above the level of the inferior tibio- fibular joint. The first wire passes trans-fibular from postero-lateral to antero-medial and should be medial to the Tibialis Anterior Muscle. The crossing wire should be inserted from postero-medial to antero-lateral, exiting lateral to the tendon of Extensor Digitorum at the widest angle neurovascular structures will permit. The third wire should be inserted from lateral to medial.



Displaced Articular Fractures

Where there is articular involvement, the frame may be applied after limited percutaneous reduction of the major articular fragments using either interfragmentary screws or the Orthofix Fragment Fixation System implants. In this situation, sufficient room (10-20mm) should be left between the articular surface and the internal fixation to place the wires.

SURGICAL PROCEDURE ON PROXIMAL TIBIA

Wire Insertion

Refer to the safe corridors for wire insertion.
The sequence of wire insertion will vary depending on the specific nature of the disorder and the surgeon's preference.

For optimal stability, three wires (either with or without olive) should be applied. The first wire can be inserted free-hand from postero-lateral to antero-medial. It is possible to insert the wire through the head of the fibula or just anteriorly **(Fig. 1A)**.

NOTE: if needed, perform reduction with an olive wire. Compact the fracture by pulling the wire gently with the tensioner under image intensifier. Stop when the fracture gap has closed without completely tensioning the wire. **(Fig. 1B)**

Attach the wire to the ring using a wire fixation bolt and nut at each end. Check that the limb is centrally placed within the ring and keep the ring parallel to the joint surface **(Fig. 2)**.

Insert the second wire from postero-medial to antero-lateral **(Fig. 3)**.

Insert the third wire from lateral to medial **(Fig. 4)**.

If necessary, to avoid bending the wire, a space between the ring and the wire can be filled with a maximum of three spacing washers; if it is larger use a post, or remove the wire and reinsert in a different position.

NOTE: it is recommended to position at least one wire on the opposite side of the ring with respect to the other two wires.

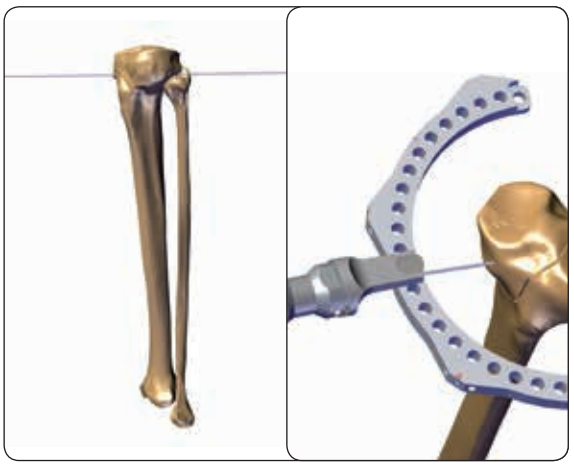


Fig. 1A Fig. 1B

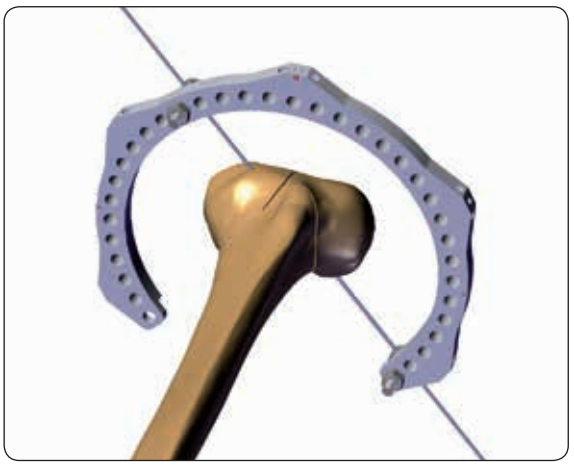


Fig. 2

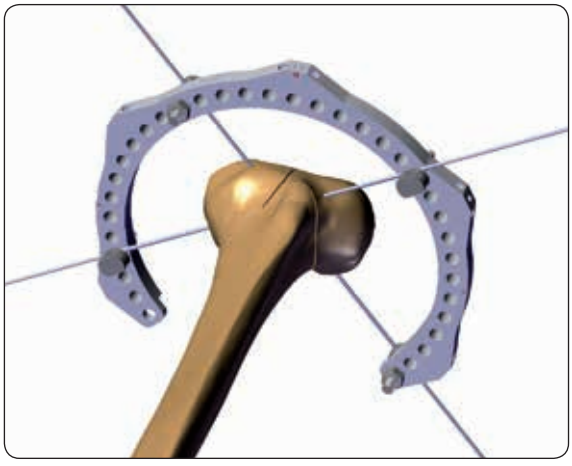


Fig. 3

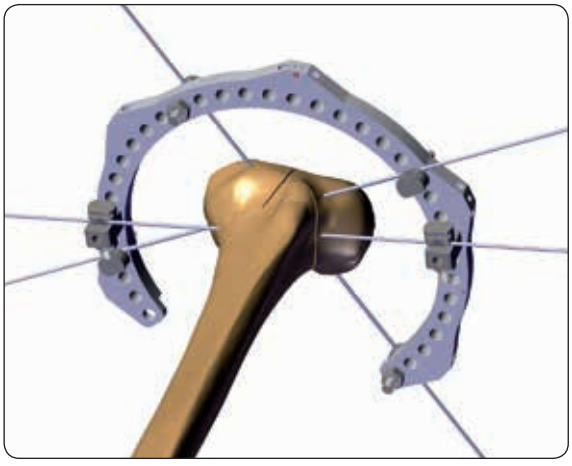


Fig. 4

Check reduction under image intensifier and complete the 5/8 ring to a full ring if necessary prior to tensioning any wires.

Wire Tensioning

Tension the first two wires simultaneously. Tighten the nut with the 10mm Wrench on the wire fixation bolt on the opposite side from where tension will be applied. Ensure the appropriate tensioner head captures the wire fixation bolt.
Based on the characteristics of the patient and the fracture, tension the wires between 100Kg and 130Kg; tighten the wire fixation nut securely prior to releasing the tensioner **(Fig. 5)**. Tension the third wire in the same way.

NOTE: in case a wire with olive is used, the tensioning must be performed from the side opposite the olive. Tension applied must be inferior to that of the other wires, avoiding excess pressure on the bone cortex.

To avoid causing injury, cut the wire ends flush with the frame, protect them with the special covers or bend them over **(Fig. 6)**.

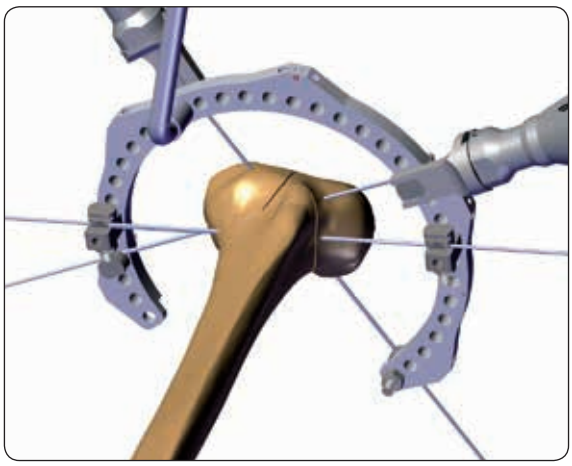


Fig. 5

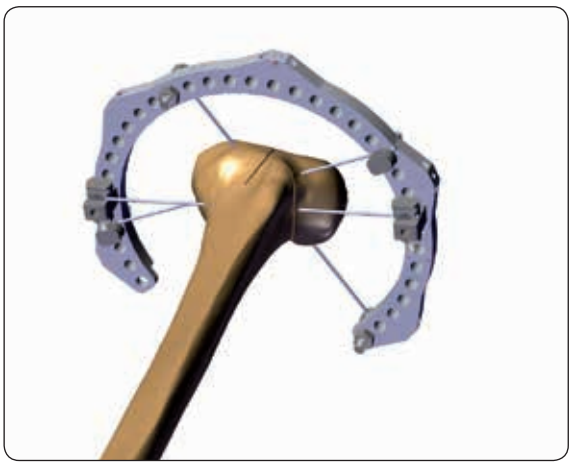


Fig. 6

Frame Construction

For the first stage two quick adjust struts are attached to the ring and partially tightened.
Connect each strut inserting the bolt into the ring and manually gently tighten it with the speed nut. Struts should not be fully closed **(Fig. 7)**.

Fig. 7

Attach the second 5/8 TL-HEX ring to the struts with the dedicated speed bolt 20mm. Adjust the position of the ring according to surgeon's preference using the side locking speed Bolt **(Fig. 8)**.

Fig. 8

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. The half pin should be fixed to the ring in a manner which 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.

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. Select the desired position and insert a 6mm screw guide in the half pin fixation bolt through the dedicated groove in the collar (the one with no marks).
2. Insert the drill guide and 4.8mm drill bit through the screw guide **(Fig. 9)**.
3. After drilling both cortices, remove the drill bit and drill guide. Wash any bone chips away with saline. Insert the desired half pin through the fixation bolt and the screw guide until it engages the second cortex **(Fig. 10)**.
4. Remove the screw guide and turn the 8mm half pin collar until the appropriate number (representing the shaft diameter) is aligned directly below the hole.

Fig. 9

NOTE: 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.

NOTE: if needed, use a trocar to locate the midline by palpation. Keep the screw guide in contact with the cortex by gentle pressure, withdraw the trocar and tap the screw guide lightly to anchor its distal end.

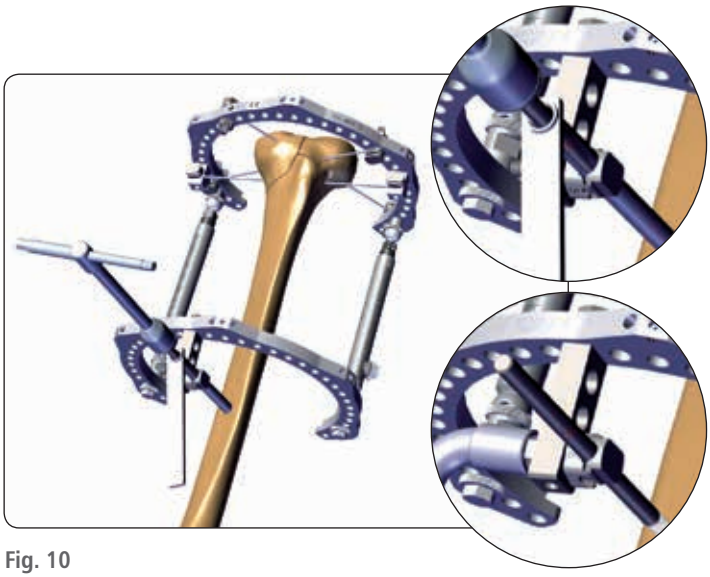


Fig. 10

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).
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 16mm 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.

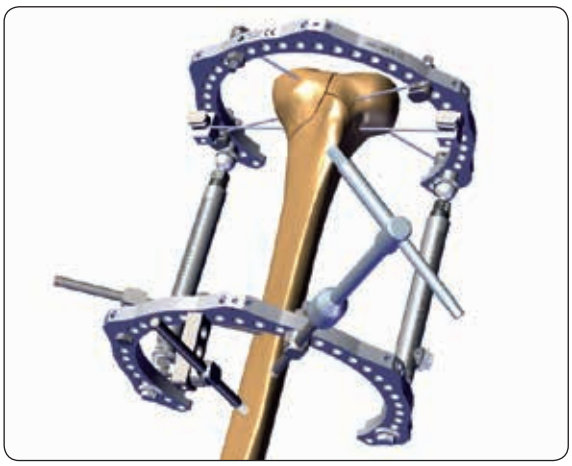


Fig. 11

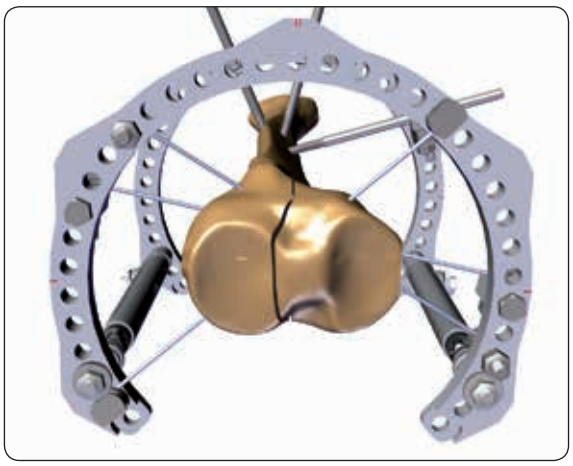


Fig. 12

After all the necessary half pins and wires have been inserted **(Fig. 11-12)**, manual reduction of the fracture is performed releasing the speed locking bolt, the speed nut and the speed bolt on each strut. After achieving a satisfactory reduction, all the nuts and bolts are tightened. Add a third quick adjust strut for definitive stabilization **(Fig. 13)**. A fourth strut can be added at surgeon's discretion.

A final micrometric adjustment and compression can be achieved by turning the plastic bushing of the struts by the desired amount, but only if the struts are parallel.

To allow for transition to the TL-HEX standard frame, in case of two 5/8 rings with the opening on the same side, a 3/8 ring must be added to one of the rings. Due to the unique feature of the TL-HEX 5/8 and 3/8 rings, this step can be done at any desired moment if bone fixation has been performed with half pins. In case of wires, the 3/8 ring can be attached only before tensioning.

Fig. 13

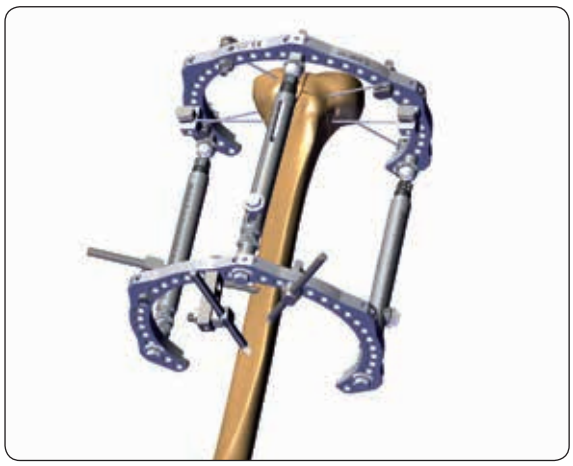


Fig. 14

MRI SAFETY INFORMATION

The Orthofix TL-HEX TRUELOK HEXAPOD SYSTEM (TL-HEX) has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Orthofix TL-HEX System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 to customer service (delivery within 7 days):
tel +39 045 6719301, fax +39 045 6719370,
e-mail: customerservice@orthofix.it

Distributed by:

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

CE 0123

Instructions for Use: See actual package insert for Instructions for Use.

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. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

ORTHOFIX®

www.orthofix.com

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