

TL-HEX GALAXY HYBRID SYSTEM

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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

A Hybrid Fixator provides stability by combining the advantages of tensioned wires and cortical screws. This document describes the application of a hybrid fixator on the proximal tibia, but the concept can be also applied on metaphyseal and articular fractures in the distal tibia and the distal femur.

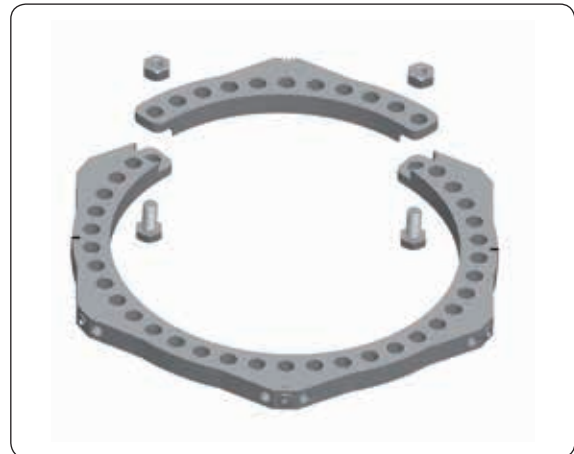


TL-HEX TrueLok Hexapod System® EXTERNAL SUPPORTS

Circular external components

TL-HEX external supports are lightweight, partially radiolucent, 9.5mm thick and made of anodized highstrength 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.

For an appropriate usage of Galaxy Fixator Hybrid Connection, only TL-HEX rings may be applied.



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.



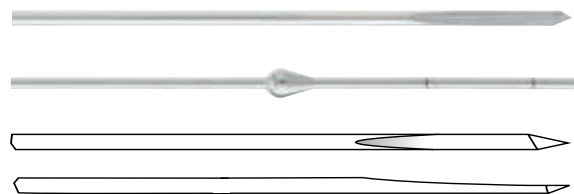
Extended Nut

Length 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.



Posts

Sizes: from 1 hole to 5 holes.

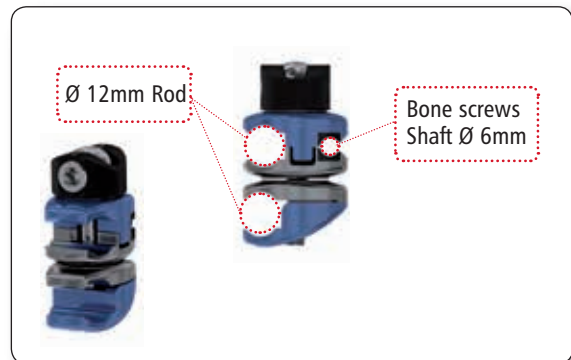
The posts have a standard female threaded base, allowing them to be secured to an external support by a 16mm bolt. The serrations on the base prevent undesirable rotation after tightening.



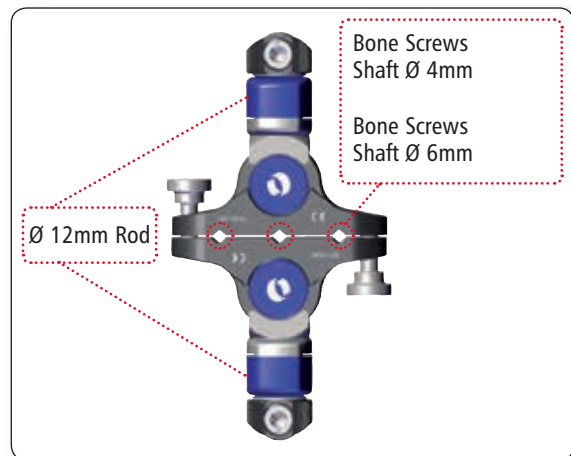
GALAXY COMPONENTS

Large Clamp for Independent Screw Placement (93010)

Allow easy and stable connection of a rod and a bone screw, a rod and a Galaxy TL-HEX Connecting Post, or two rods.



Double Multiscrew Clamps Large (93040)



Galaxy TL-HEX Connecting Post

(93031) Galaxy TL-HEX Connecting Post L50mm D12mm



(93032) Galaxy TL-HEX Connecting Post L100mm D12mm



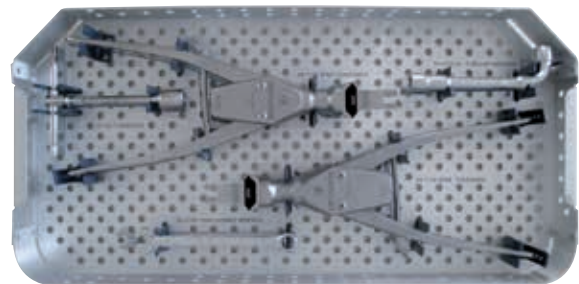
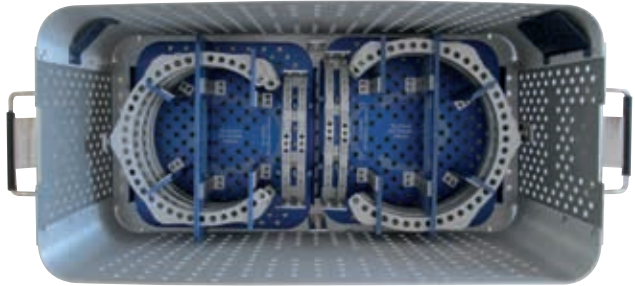
Rods Diameter 12mm (932XX)



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	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	TL+ Universal Half Pin Fixation Bolt 4mm - 6mm	15
54-11530		
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 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

Out of tray

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 tray

Additional components

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
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
30017	Allen Wrench 5mm	1

Galaxy fixator

Part Number	Description	Q.ty
93010	Large Clamp	3
93040	Large Double Multiscrew Clamp	1
93031	Galaxy TL-HEX Connecting Post L50mm D12mm	3
or		
93032	Galaxy TL-HEX Connecting Post L100mm D12mm	3

Rods

Part Number	Description	Q.ty
932100	Rod 100mm long	2
932150	Rod 150mm long	2
932200	Rod 200mm long	2
932250	Rod 250mm long	2
932300	Rod 300mm long	2
932350	Rod 350mm long	2
932400	Rod 400mm long	2
99-932450	Rod 450mm long, sterile*	2
99-932500	Rod 500mm long, sterile*	2
99-932550	Rod 550mm long, sterile*	2
99-932600	Rod 600mm long, sterile*	2
99-932650	Rod 650mm long, sterile*	2

* Special order only



NOTE: All clamps, posts and rods are also available single-packed and sterile. They can be ordered using the above code numbers preceded by 99- (e.g. 99-93010).

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

GALAXY HYBRID SYSTEM SURGICAL PROCEDURE

TL-HEX ring application

SAFE CORRIDORS

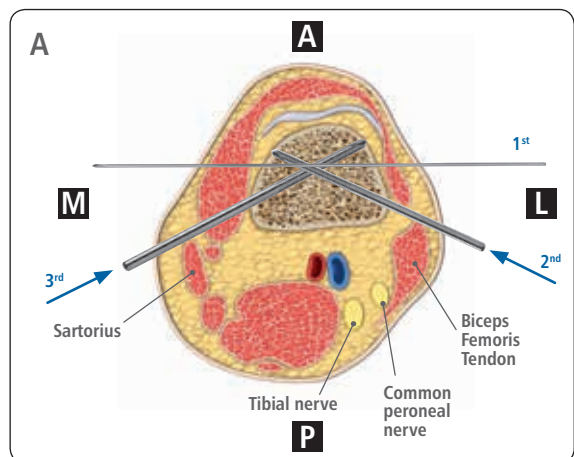
In figures A, B and C safe corridors for the insertion of the fixation elements are represented.

Distal Femur

Wire and screw 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 insertion is therefore crucial.

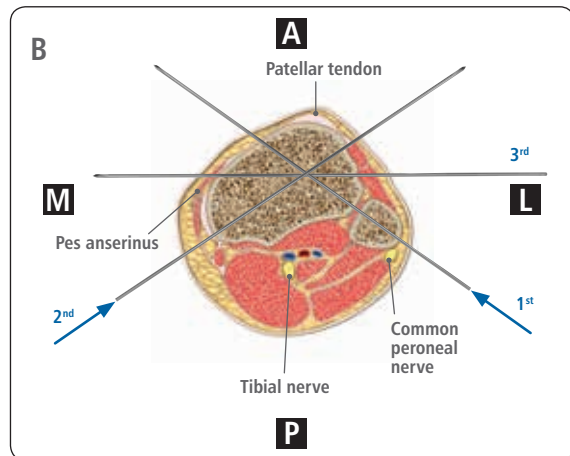


Firstly insert a wire from lateral to medial. Then insert two screws: one screw from postero-lateral to anteromedial, anterior to the Biceps Femoris Tendon, and one screw from postero-medial to anterolateral, anterior to the Sartorius. Wire and screws should be inserted with the knee flexed.



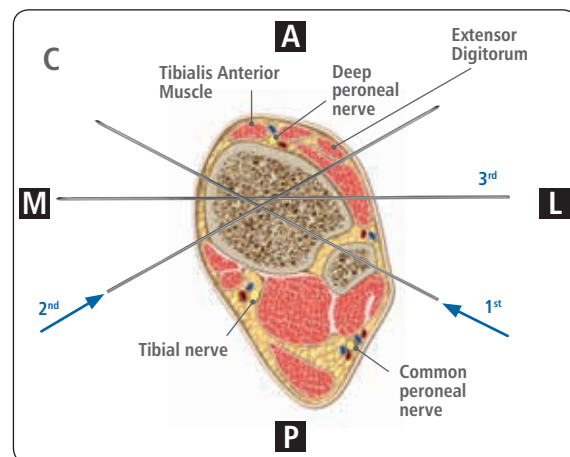
Proximal tibia

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 1 cm 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

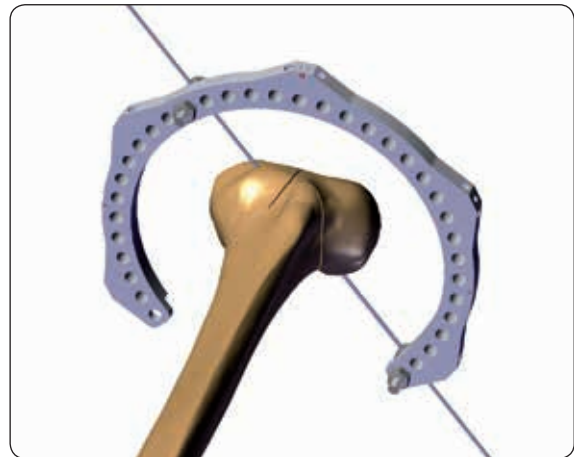


Fig. 2

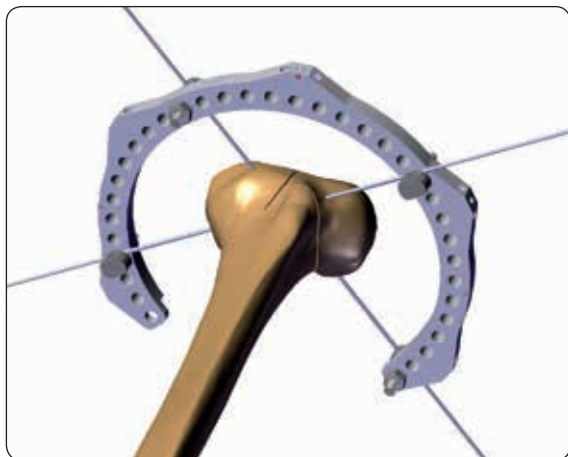


Fig. 3

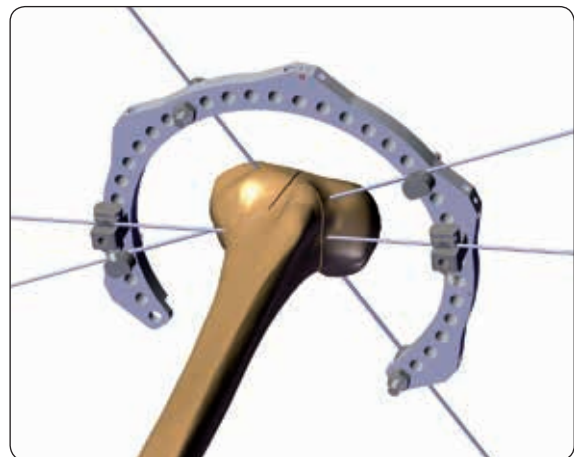



Fig. 4

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, inserting temporarily a 3/8 ring to aid in avoiding deformation during tensioning. 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).

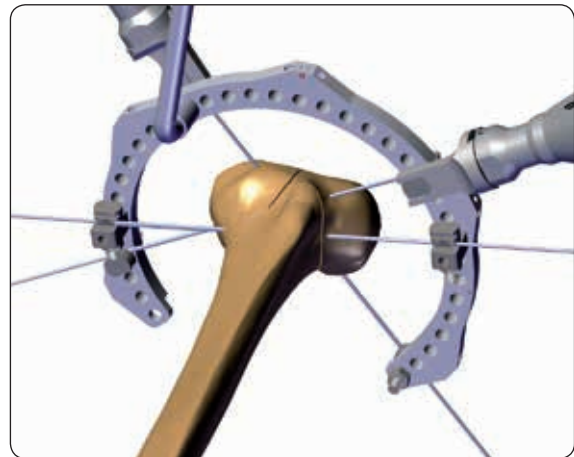
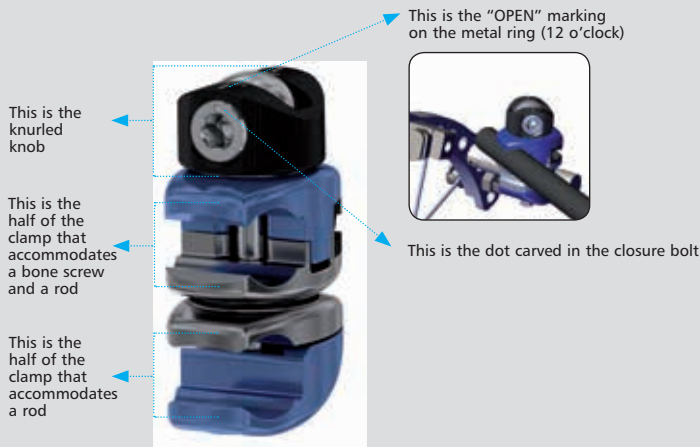


Fig. 5



Fig. 6

CLAMP CLOSURE PROCEDURES



1 FRAME ASSEMBLY



Start position - Clamp open

The dot on the bolt must be in line with the "OPEN" marking on the metal ring (12 o'clock)



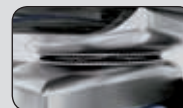
The two halves of the clamp are separated. Rods and bone screws can be easily inserted with snap-in system

2 PRELIMINARY CLOSURE AND FRACTURE REDUCTION



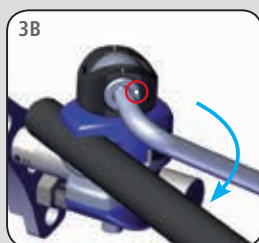
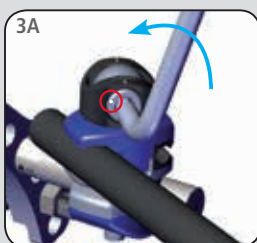
Pre-closure by hand

The dot on bolt must be kept in line with the "OPEN" marking on the metal ring (12 o'clock), while by hand the knurled knob is turned clockwise



The two halves of the clamp are now tightened closed. Rods and bone screws cannot be inserted anymore

3 DEFINITIVE FRAME LOCKING



Final closure

The 5mm Allen wrench is inserted in the bolt and is turned either clockwise (3 o'clock - 3B) or counter clockwise (9 o'clock - 3A). This engages a cam for final tightening



Now the dot on cam has moved accordingly

Galaxy application

Each screw's position should be planned with regard to zone of injury to reach maximum mechanical stability with bicortical purchase by the screw threads. Tibial screws are preferentially inserted in the sagittal (anteroposterior) plane, approximately 1 cm medial to the tibial crest.

Pre-assemble the double large multiscrew clamp with two or three screw guides (as needed). Make sure that the screw guides are fixed in the clamp at the same depth to ensure that, when inserted down to the bone, they are at 90 degrees with all the guide tips touching the bone. (Fig. 7).

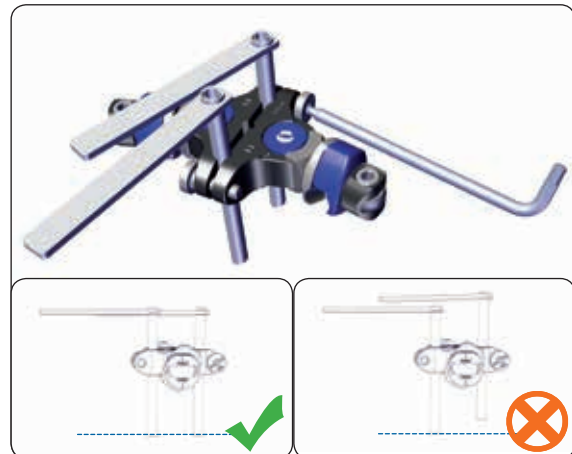


Fig. 7

Use the clamp as a template to insert the screws:

- Make an incision through the skin
- Insert the screw guide perpendicular to the tibia making sure it touches the bone
- Insert the drill guide (4.8mm) and drill bit (4.8mm) through the screw guide (Fig. 8)
- Drill both cortices, cooling with saline
- Remove the drill bit and drill guide and wash any bone chips away with saline
- Manually insert the bone screw with the T-Wrench into one of the outer holes of the clamp (Fig. 9)



Fig. 8

Once all screws are inserted, remove the screw guides and close the clamp.

Where two screws are inserted, use the outer holes of the clamp. Generally in adults three screws are recommended.

It is important that the clamp is locked firmly over the screws about 30mm from the skin.



Fig. 9

Attach two Galaxy TL-HEX Connecting Posts to the ring (Fig. 10).

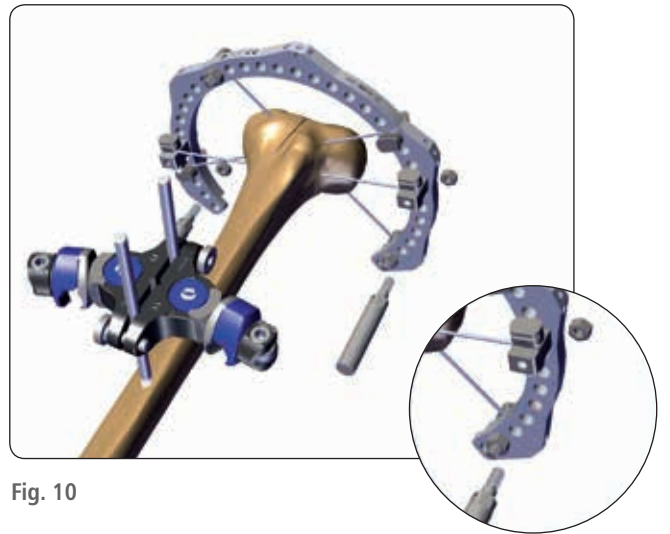


Fig. 10

Attach two large clamps to the Galaxy TL-HEX Connecting Posts (Fig. 11).



Fig. 11

Connect them to the central multi-screw clamp through rods of suitable length. Then manually lock all clamps by turning the knurled metal ring clockwise. Lock all clamps firmly by tightening the cams with the Allen Wrench 5mm (Fig. 12).



Fig. 12



Fig. 13

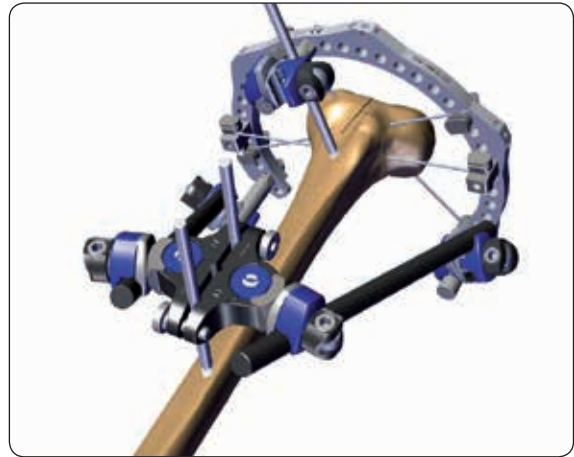


Fig. 14



NOTE: To increase the mechanical stability, an additional screw can be inserted centrally approximately 25mm from the ring. Connect the third screw to the ring with a Galaxy TL-HEX Connecting Post and a large clamp. (Fig. 14)

POST OPERATIVE MANAGEMENT

Depending on fracture-type, and reduction as well as patient characteristics, active and passive mobilization may be commenced shortly after surgery. Progressive weight bearing and physiotherapy should be established according to the surgeon evaluation of the fracture stability and of the information derived from radiological assessment.

During the post-operative period, the elasticity of the wires will allow sufficient micromovement at the fracture site to stimulate callus formation.

MRI SAFETY INFORMATION

The Orthofix Galaxy Hybrid System 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 Galaxy Hybrid System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

If your leaflet does not include the text in your language, please refer to the electronic instructions.

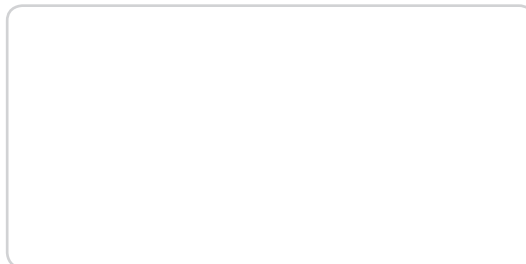
Electronic Instructions for use available at the website
<http://ifu.orthofix.it>

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

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