

TL-HEX™ GALAXY FIXATION™ HYBRID SYSTEM

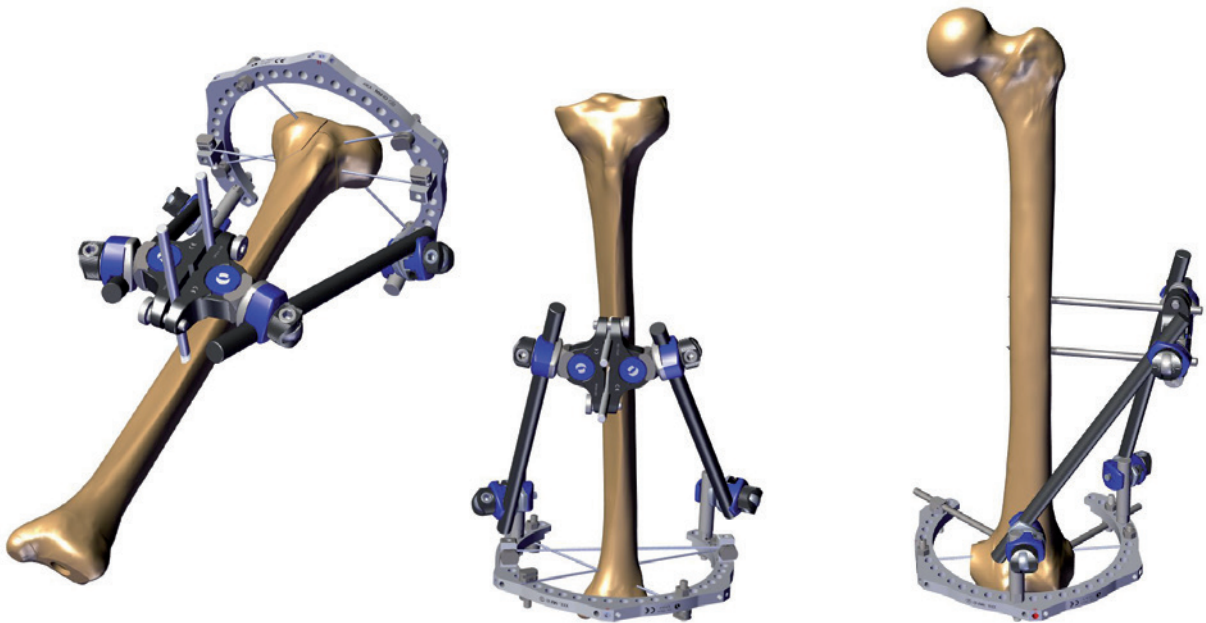
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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please kindly refer to the product IFU PQGAL, 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.

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.

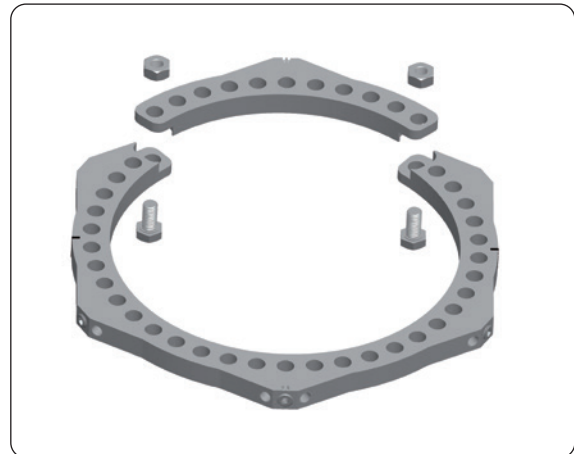


TL-HEX™ TrueLok Hexapod System[®] EXTERNAL SUPPORTS

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

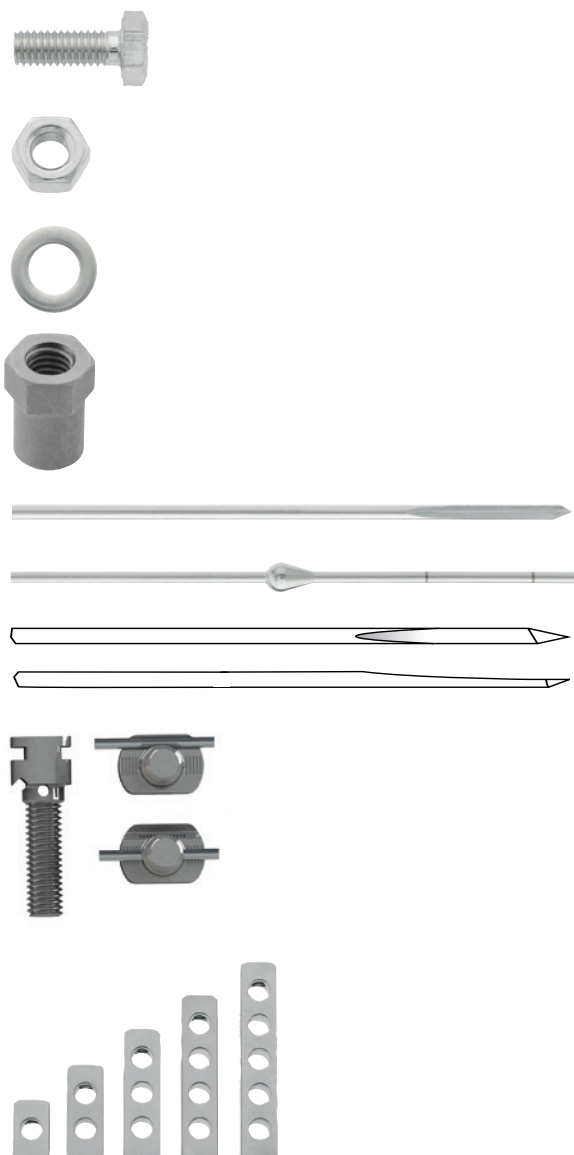
1.8mm diameter wires are available in two types: smooth and wires with olive. The latter provide a stop at the bone interface. Both wire styles have a bayonet-shaped, eccentric tip, which efficiently drills through both cortical and cancellous bone without generating excessive heat.

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

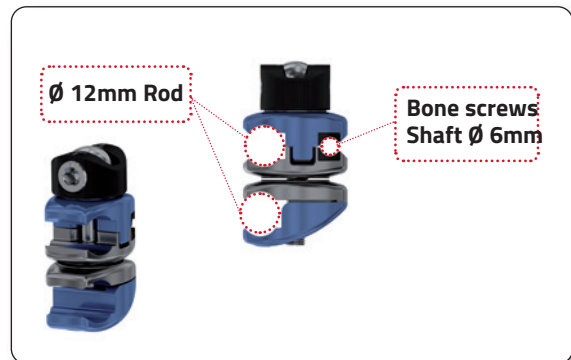
Sizes: from 1 hole to 5 holes. The posts have a standard female threaded base, allowing them to be secured to an external support by a 16mm bolt. The serrations on the base prevent undesirable rotation after tightening.



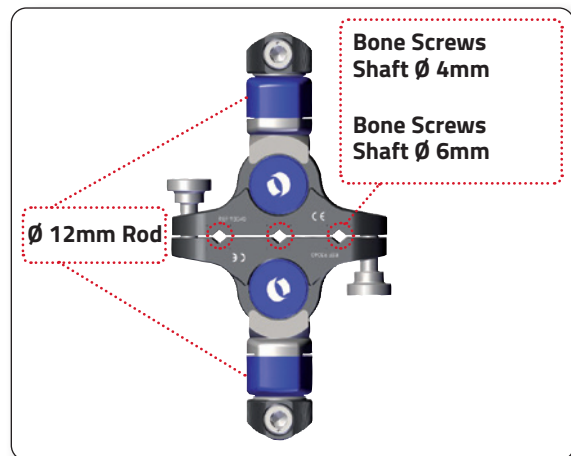
GALAXY FIXATION™ COMPONENTS

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

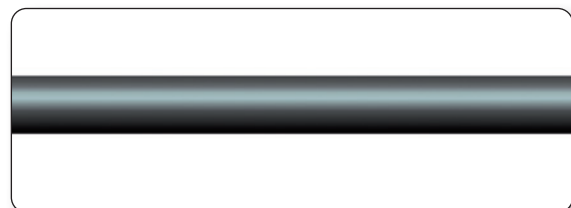
(93031) Galaxy TL-HEX Connecting Post L50mm D12mm



(93032) Galaxy TL-HEX Connecting Post L100mm D12mm



Rods Diameter 12mm (932XX)



EQUIPMENT SUGGESTED

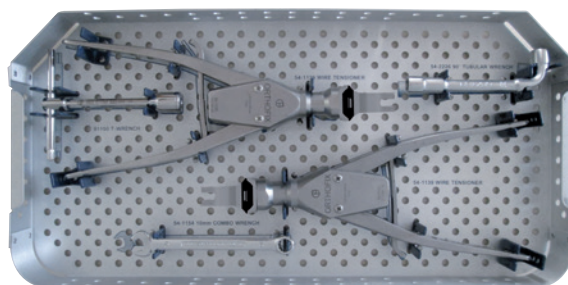
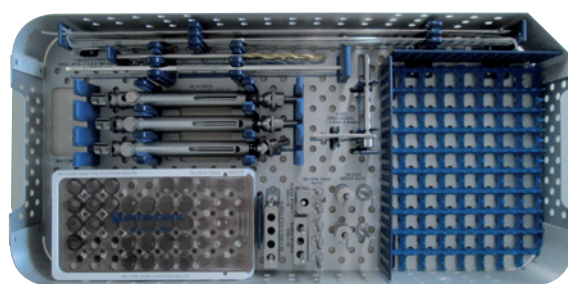
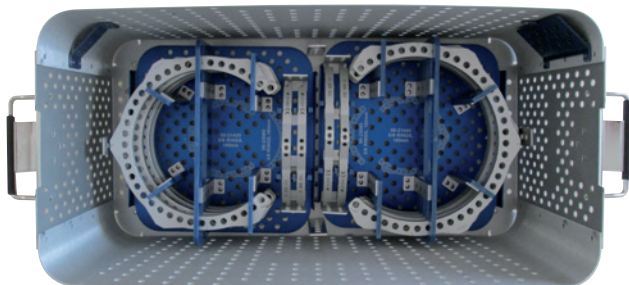
Trauma Tray, TL-HEX, code 30110129 (empty)

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	
54-11530	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 or	Short Graduated Drill Bit 4.8X180mm	1
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

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*

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*

The TL-HEX™ Galaxy Fixation™ Hybrid 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.

PROCALLUS™ 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.

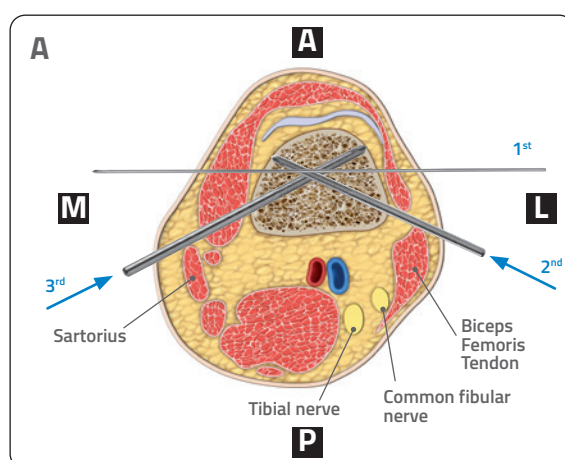
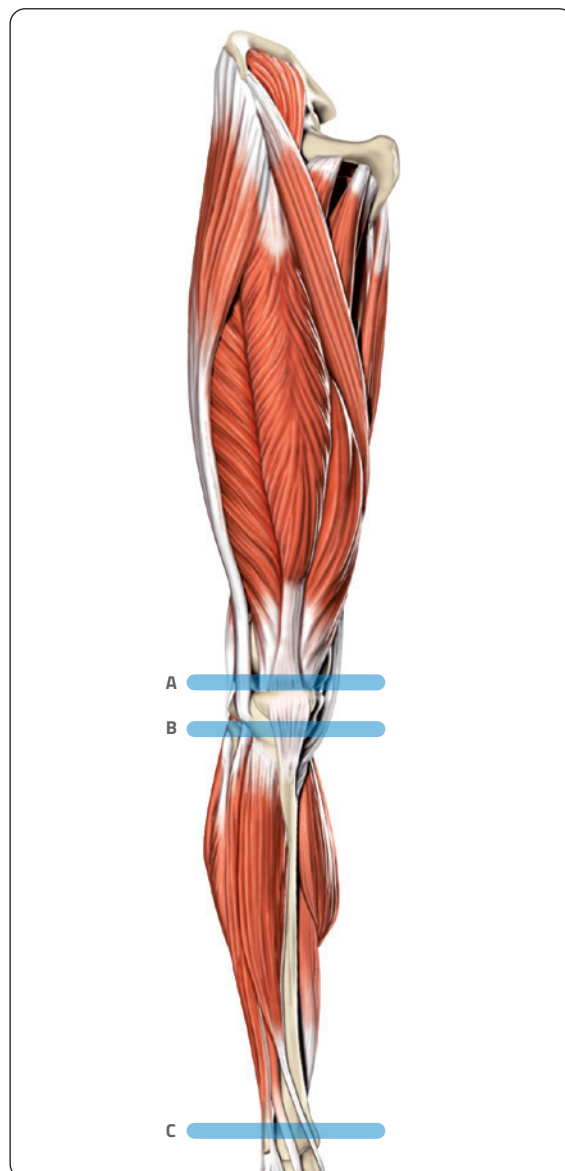


PRECAUTION: Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the vital structures.

Distal Femur

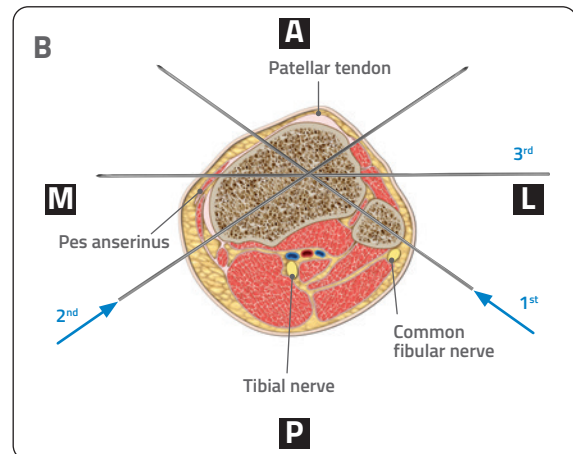
Wire fixation in the distal femur is challenging due to the important periarticular structures present. Furthermore, narrow wire crossing angles produce instability in the sagittal plane. Correct wire insertion is therefore crucial.

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



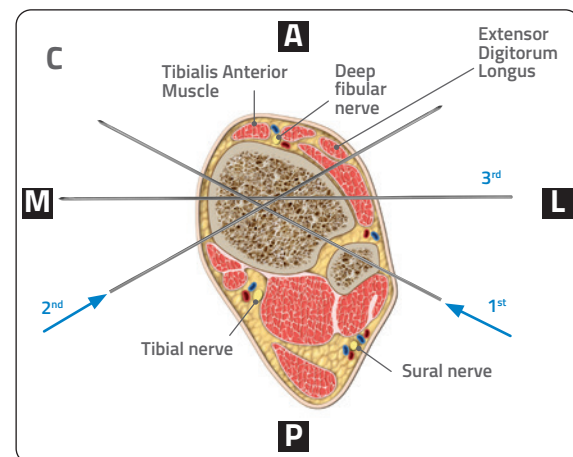
Proximal tibia

When inserting wires in the proximal tibia, the head of the fibula is an important landmark, since the Common Fibular 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 Longus 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**).

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**).



PRECAUTION: 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.



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

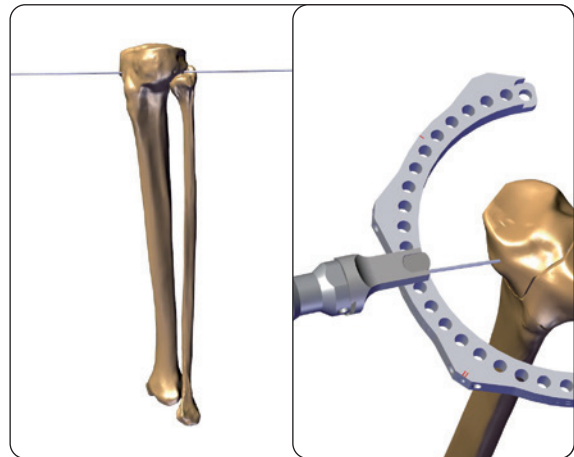


Fig. 1A

Fig. 1B

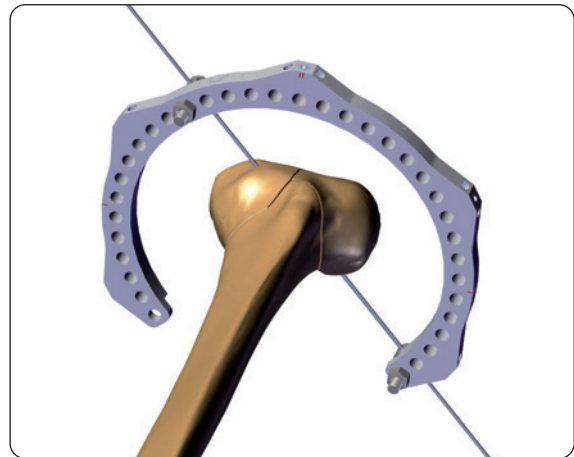


Fig. 2

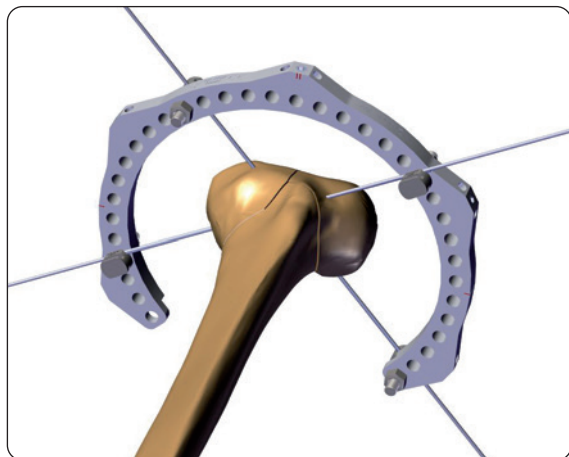


Fig. 3

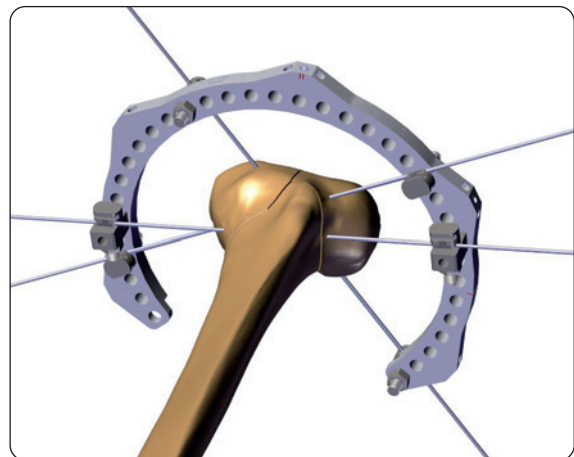


Fig. 4

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



PRECAUTION: During and after insertion of the implants, ensure their correct positioning under image intensification.

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 up to 130Kg; tighten the wire fixation nut securely prior to releasing the tensioner (**Fig. 5**). Tension the third wire in the same way.

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.



PRECAUTION: 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.

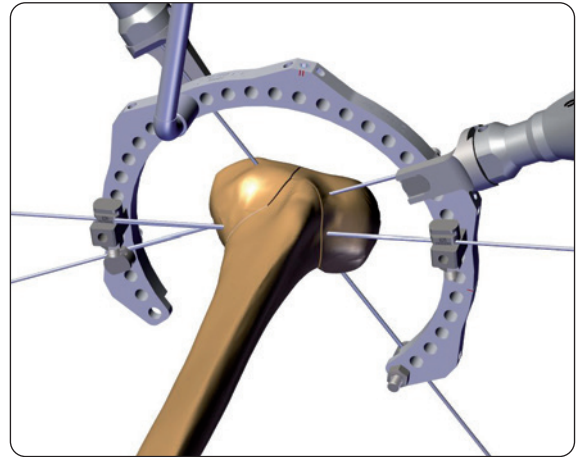


Fig. 5

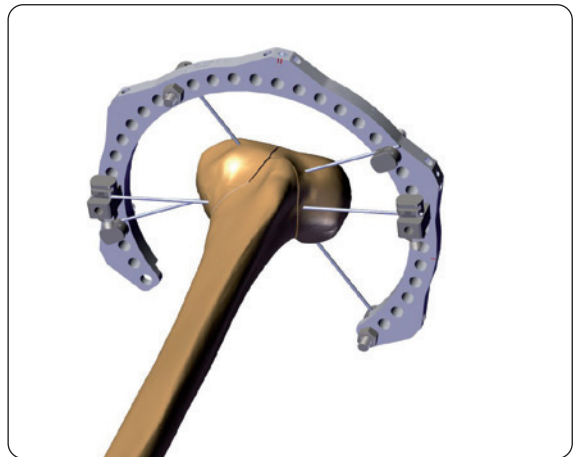
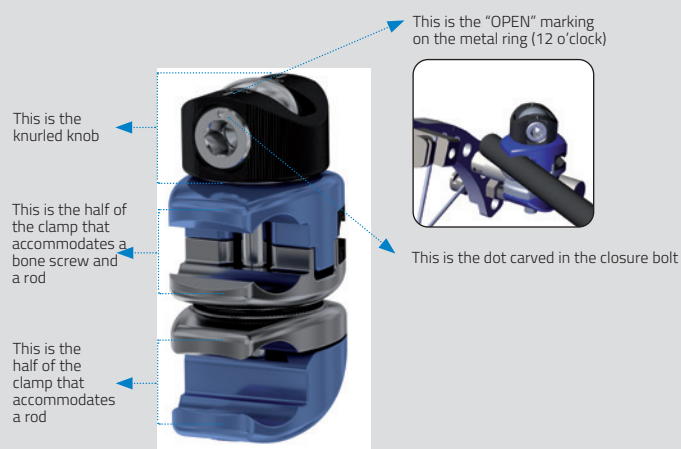


Fig. 6

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



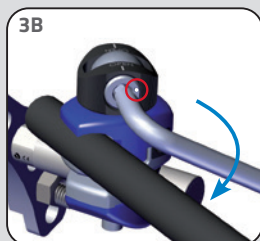
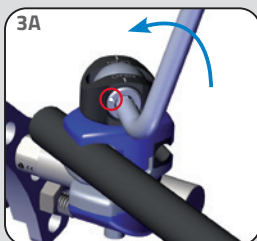
Pre-closure by hand

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 Fixation™ 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 1cm 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**).



PRECAUTION: Diaphyseal bone screws should always be inserted perpendicular to and in the centre of the bone axis to avoid weakening it.



PRECAUTION: To ensure the correct locking of the multi-screw clamp use always 2 screws and ensure that they are of the same diameter.

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**)

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.



WARNING: The fixator should be applied at a sufficient distance from the skin to allow for post-operative swelling and for cleaning, remembering that the stability of the system depends upon the bone-fixator distance. If the fixator is sited at a distance of more than 4cm from the bone the surgeon will decide on the number of rods and bone screws needed to achieve the appropriate frame stability.

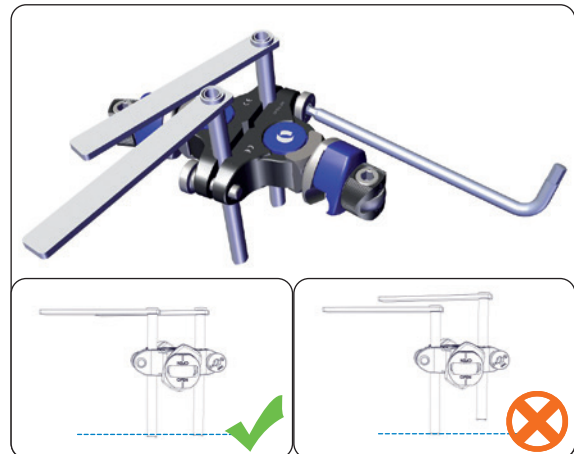


Fig. 7

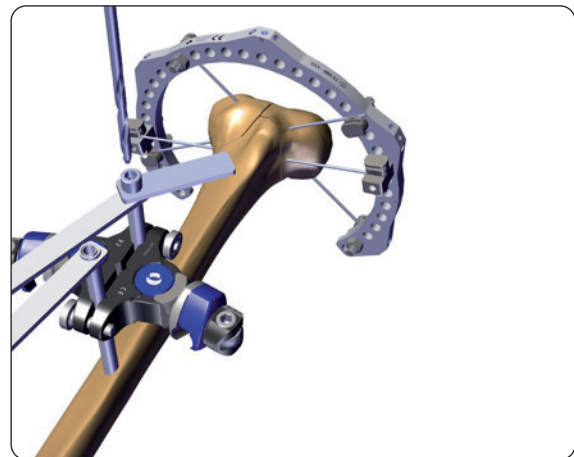


Fig. 8

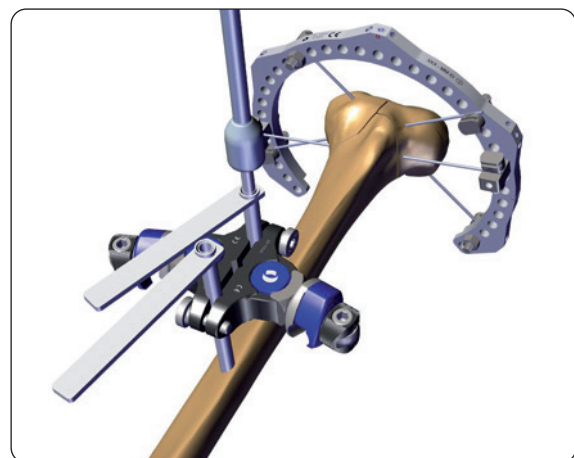


Fig. 9

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

Secure the end of the Galaxy TL-HEX connecting Post (length 50mm or 100mm and diameter 12mm; hereinafter "Post") to the ring in the standard manner with the provided nut. It is recommended to connect the two Posts to the ring in opposite position with respect to the ring center, as far as possible one from each other. The positions of the Posts may vary depending from ring diameter and wire placement. The use of the short Post (50mm) is suggested for more stability.

Tighten the nut with two wrenches.

Place the second Post in the most appropriate position (ideally on the opposite side of the ring) compared to the first Post and the previously assembled frame components.

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

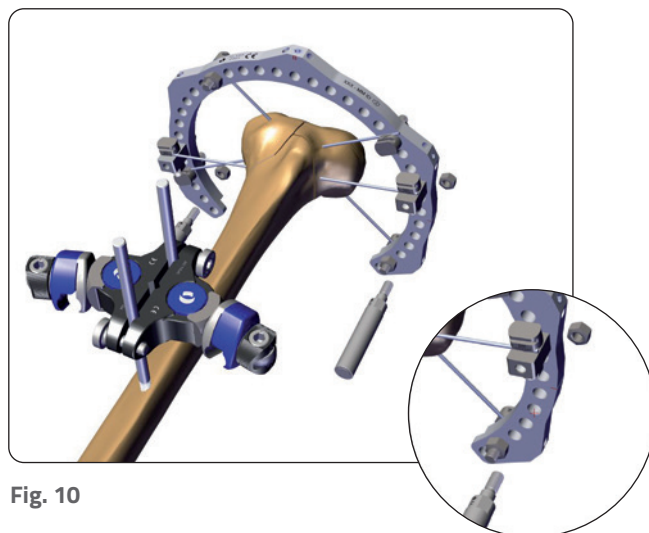


Fig. 10

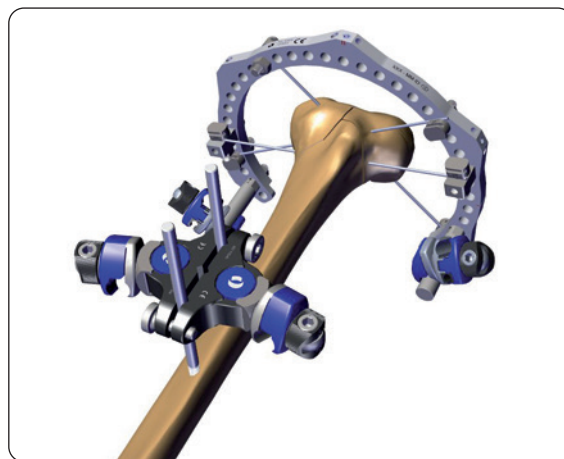


Fig. 11

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**).

If the Large Double Multiscrew Clamp is used, then a single blue clamp must be used (diameter of the rod is 12mm) and if the Medium Double Multiscrew Clamp is used, then a transition clamp yellow/blue must be used (diameter of the rod is 9mm).

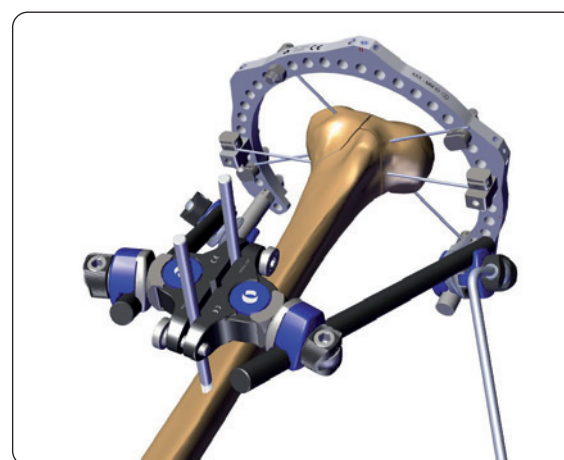


Fig. 12

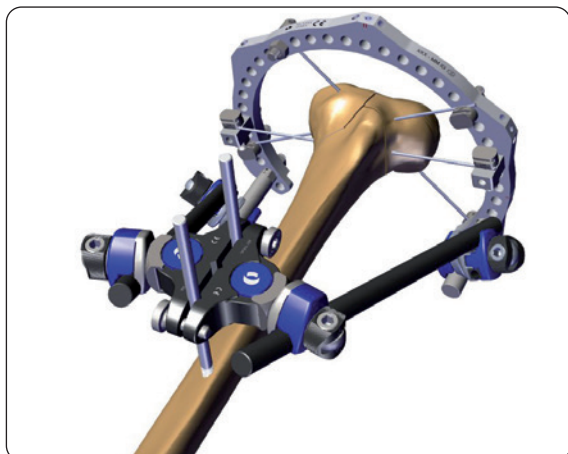


Fig. 13

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)

Optional Additional Step

7. The use of a third Post is optional when using the Large Double Multiscrew Clamp and 12mm rods, whereas it is mandatory in combination with the Medium Double Multiscrew Clamp and 9mm rods.
8. Place the third Post in a central position between the other two.
9. Connect the third Post with a Galaxy Large Clamp and use it as a template to insert the bone screw in the most appropriate direction. Then tighten the Galaxy Large Clamp as described above.

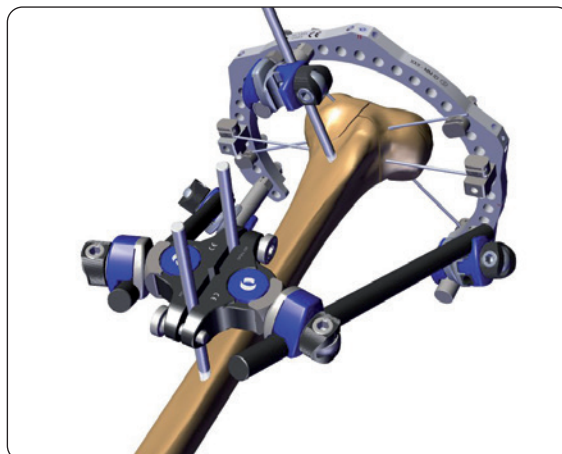


Fig. 14

MRI SAFETY INFORMATION

The TL-HEX™ GALAXY FIXATION™ 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 TL-HEX™ GALAXY FIXATION™ Hybrid System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

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.



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