

TL-HEX PROCALLUS HYBRID SYSTEM

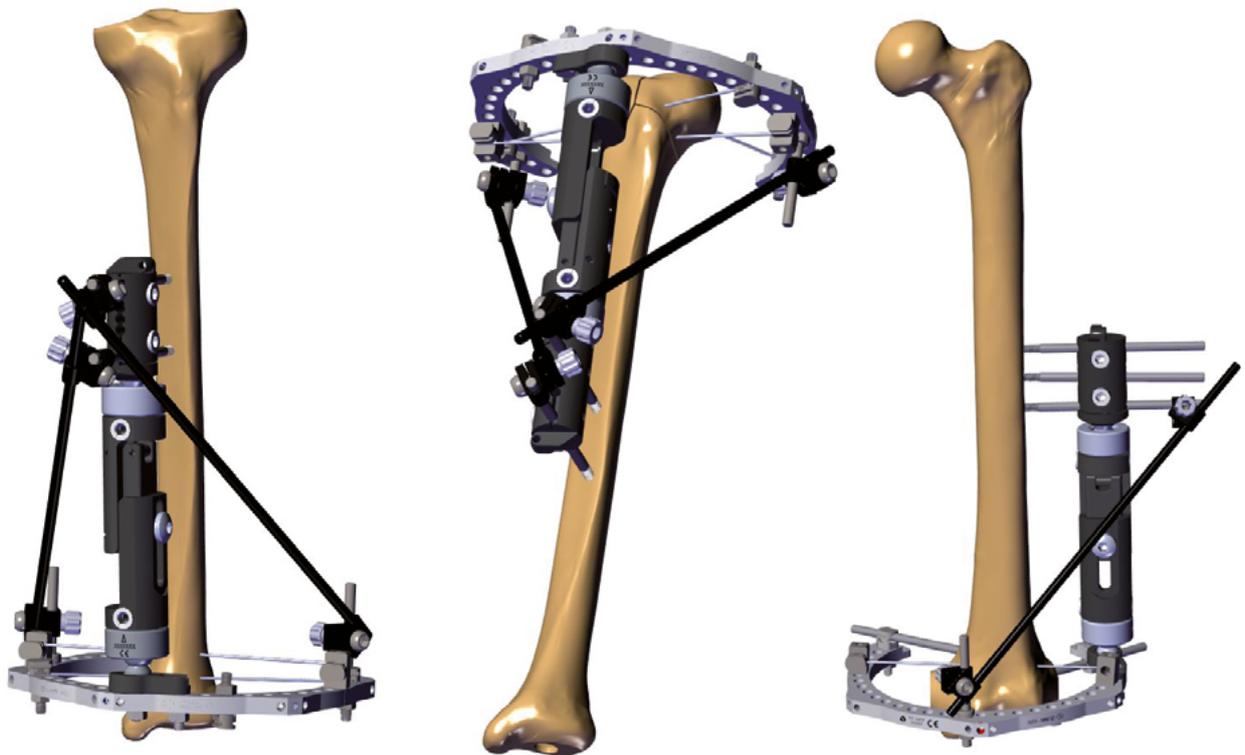
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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each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

INTRODUCTION

A Hybrid Fixator provides good 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 applied also on metaphyseal and articular fractures in the distal tibia and the distal femur.

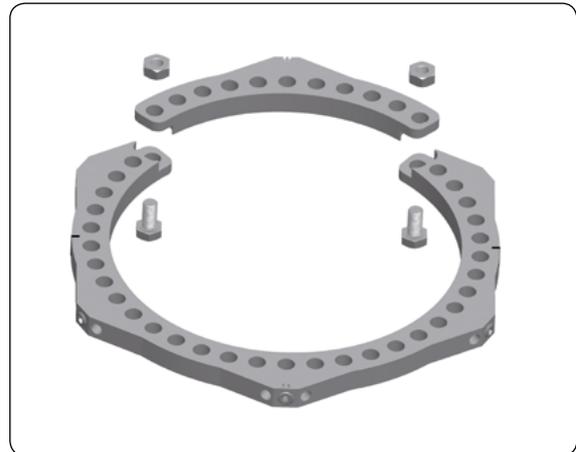


**TL-HEX TrueLok Hexapod System®
EXTERNAL SUPPORTS**

Circular external components

TL-HEX external supports are lightweight, partially radiolucent, 9.5mm thick and made of anodized high-strength aircraft grade aluminum. They are offered in 10 diameters (from 100mm to 300mm). Full rings can be obtained by attaching a 3/8 ring to a 5/8 ring using 2 bolts and 2 nuts.

For an appropriate usage of ProCallus Fixator Hybrid Connection, only TL-HEX rings must 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

Lengths: 12mm, 16mm, 20mm.



Nuts



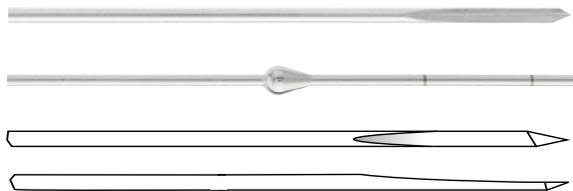
Spacing Washer

2mm thick.



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.



PROCALLUS

ProCallus Fixator Kits

Complete with appropriate Compression-Distractor Unit and Allen Wrench 6mm.

1

90001 Long

(27.6cm between outermost screws when fixator body fully closed: extends by 8cm).



2

90000 Standard

(23.6cm between outermost screws when fixator body fully closed: extends by 4cm).



3

90028 Short

(21.6cm between outermost screws when fixator body fully closed: extends by 2.75cm).



If the fixator is reused, cams and bushes should be replaced.

80022 - ProCallus Fixator Hybrid Connection



90038 Supplementary Screw Holder Clamp



81043 Supplementary Screw Holder Bar

RadioLucent Length 300mm



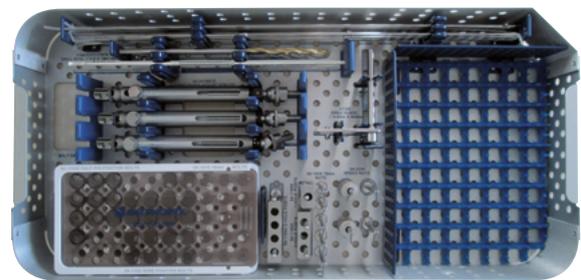
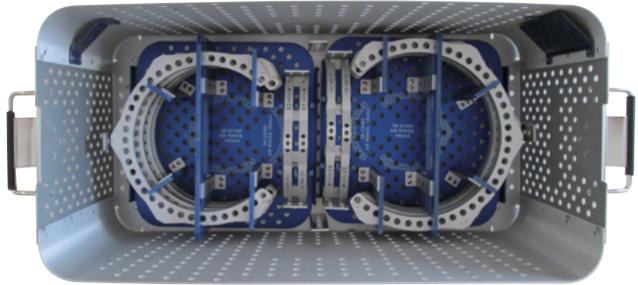
80042 Posts Length 50mm



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



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

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

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
10025	Torque Wrench 6mm	1
11004	Trocar	1

Diaphyseal fixator

Part Number	Description	Q.ty
90001	Procallus Long	1
90000	Procallus Standard	1
90028	Procallus Short	1
80022	Procallus Fixator Hybrid Connection	1
90038	Supplementary Screw Holder Clamp	4
80042	Post Length 50mm	2
81043	Supplementary Screw Holder Bar Radiolucent 300mm	2
10017	Allen Wrench 6mm	1

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

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.

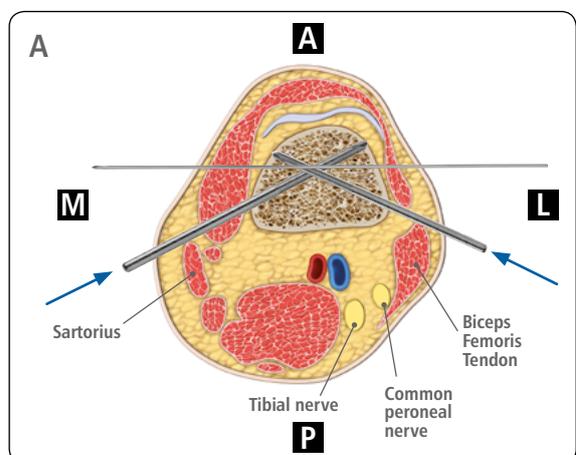
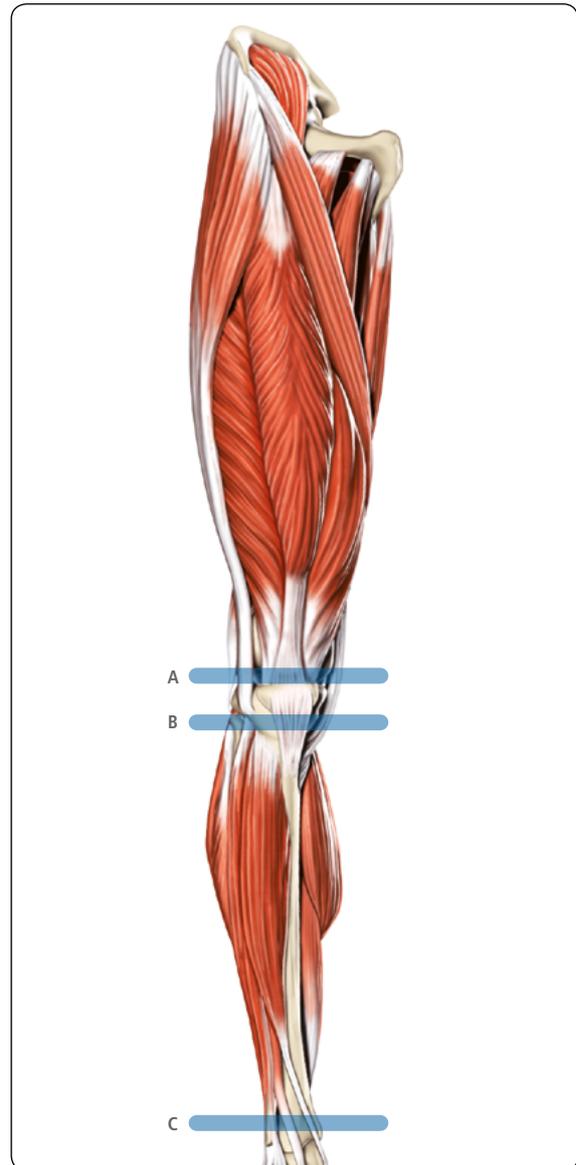


PRECAUTION: Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the vital structures.

Distal Femur

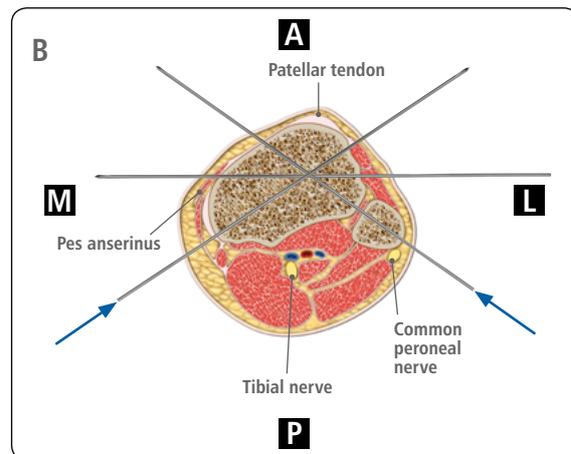
Wire fixation in the distal femur is challenging due to the important periarticular structures present. Furthermore, narrow wire crossing angles produce instability in the sagittal plane. Correct wire insertion is therefore crucial.

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.



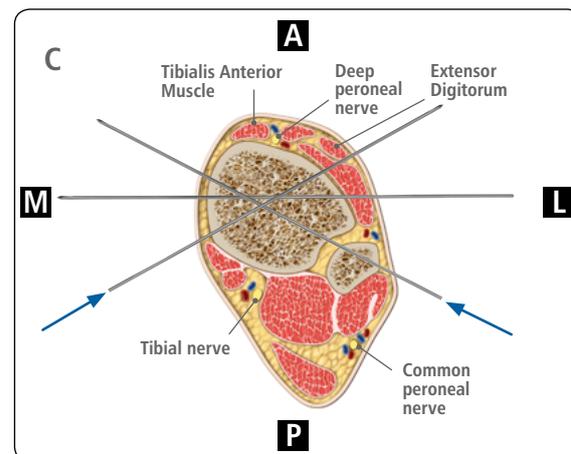
Proximal tibia

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

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.

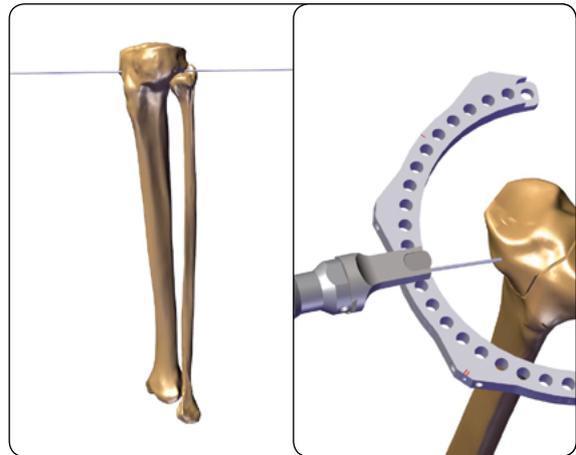


Fig. 1A

Fig. 1B

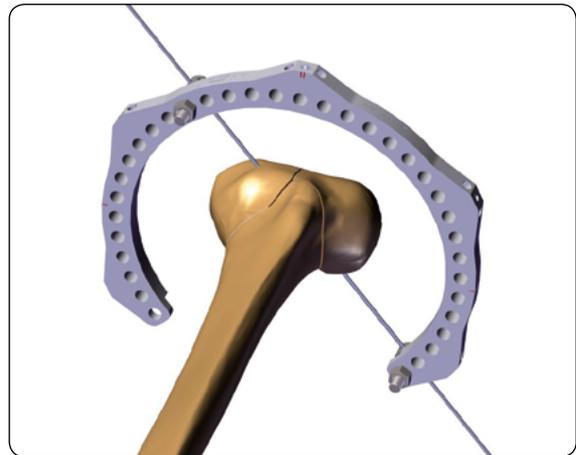


Fig. 2

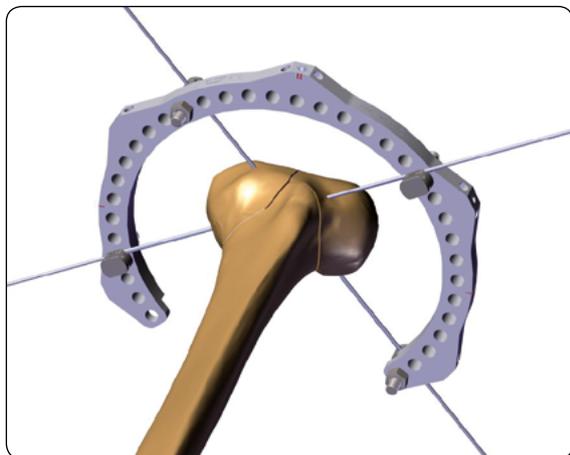


Fig. 3

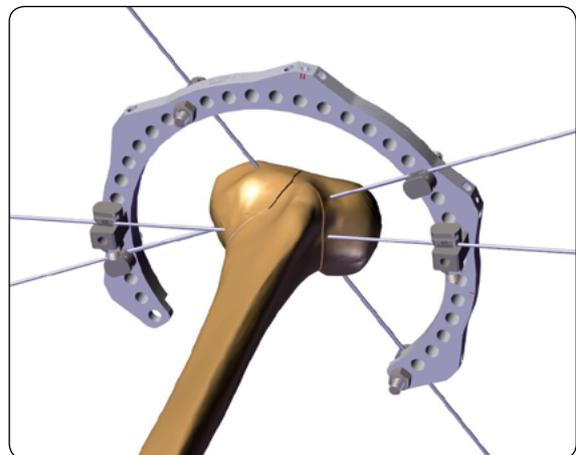


Fig. 4

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. Tighten the nut on the wire fixation bolt with the 10mm Wrench 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 to the olive. Tension applied must be inferior to that of the other wires, thus avoiding excessive 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.

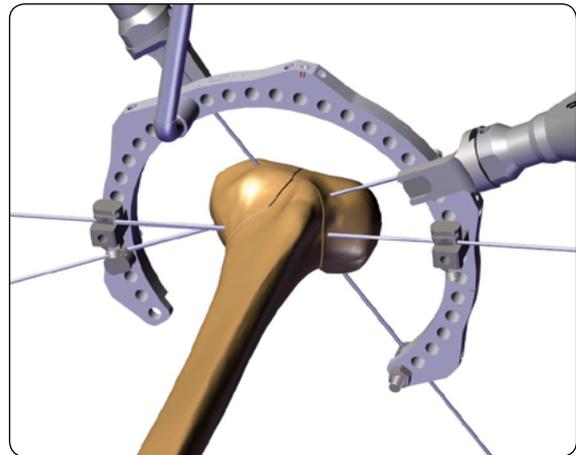


Fig. 5

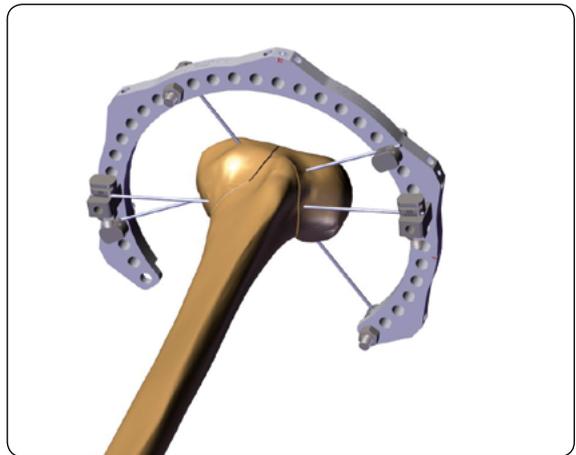


Fig. 6

Procallus application

The ProCallus fixator comes in three sizes: short, standard and long. Check that the appropriate size is assembled correctly before attaching the fixator to the TL-HEX ring.

PROCALLUS FIXATOR HYBRID CONNECTION ASSEMBLY

Insert one cam into the body of the device with the dot facing the adjacent clamp site.

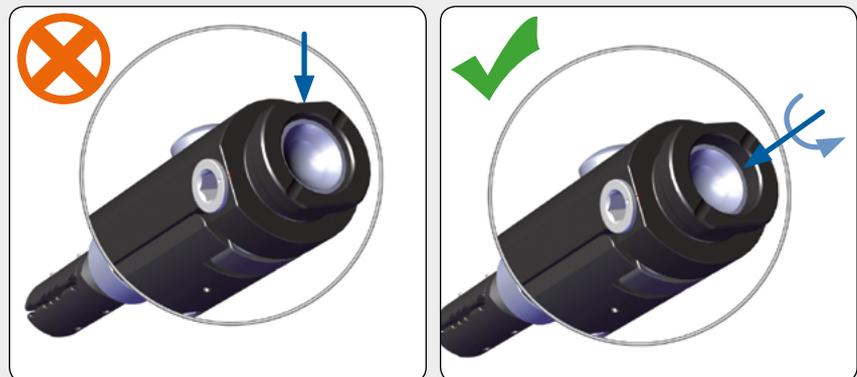
The two Allen Wrench fitting points must be positioned on the same side.



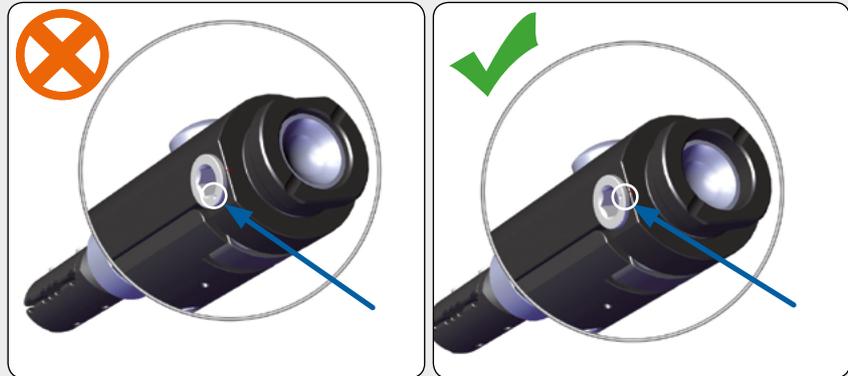
Insert the bush with its groove facing the cam.



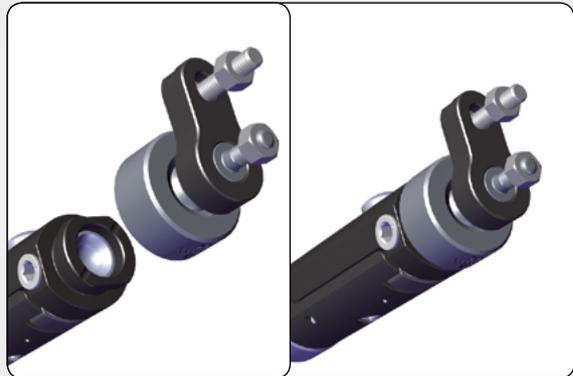
Rotate the bush with the finger to ensure that the cam is seated in its groove.



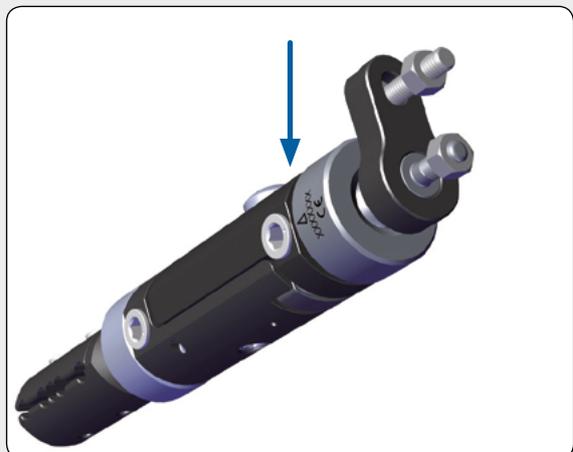
Turn the cam so that its dot is facing the open end of the fixator. Now hold the cam in place with the thumb.



Take up the ProCallus Fixator Hybrid Connection and line up body and clamp (note squared sides). The dot on the cam should point towards the clamp. Insert body into clamp (bayonet-type locking).



Using slight pressure, rotate the collar 90° to line up its arrow with the dot on the cam. The ring then closes with a click.



Position the fixator parallel to the long axis of the bone and attach it to the ring. Lock the two nuts with the 10mm Wrench (Fig. 7). Ensure all cams and locking nuts are accessible for tightening. Check that the fixator body is neither fully closed nor fully open.



Fig. 7

Lightly tighten the two ball-joints with a 6mm Allen Wrench to hold the fixator body in position (Fig. 8).

Diaphyseal Screw Insertion

The clamp acts as its own template for the insertion of the bicortical screws. Insert the number of screws required to ensure good stability. For adults, 3 screws are recommended. When only two screws are to be inserted, it is recommended to use clamp seats 1 and 5. When inserting three screws use seats 1, 3 and 5. Open the clamp cover to insert the screw guides and close the cover firmly to keep them parallel. Check that the fixator body is parallel to the bone axis, and the screw guides are perpendicular to the bone axis. Using a 4,8mm drill guide and drill bit, drill both the first and second cortices (Fig. 9A). Remove the drill guide, wash any bone chips away with saline, and manually insert the bone screw with the T-Wrench (Fig. 9B). Repeat this procedure to insert all the screws. After all the screws have been inserted, remove the screw guides before finally tightening the clamp cover.



Fig. 8

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.



WARNING: Axial displacement may occur if the body of the fixator is not in line with and parallel to the bone.



WARNING: Medial or lateral translation may occur if the body of the fixator is not placed parallel to the diaphysis.



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

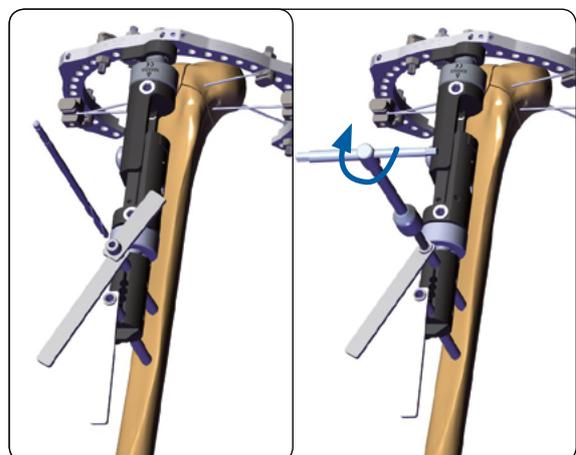


Fig. 9A

Fig. 9B

With both cams loosened, final reduction is now carried out. The cams are locked firmly with the 6mm Allen Wrench by turning them **CLOCKWISE**. The micromovement locking nut and central body locking nut are also locked with the 6mm Allen Wrench. Final locking of the ProCallus ball-joints is performed using the Torque Wrench which must be turned **IN A CLOCKWISE DIRECTION ONLY**. A click indicates the correct torque (**Fig. 10A**).

Use the Torque Wrench for final locking of ProCallus ball-joints only.



WARNING: Any attempt to unlock the cam or any screw using the torque wrench will damage its gearing.

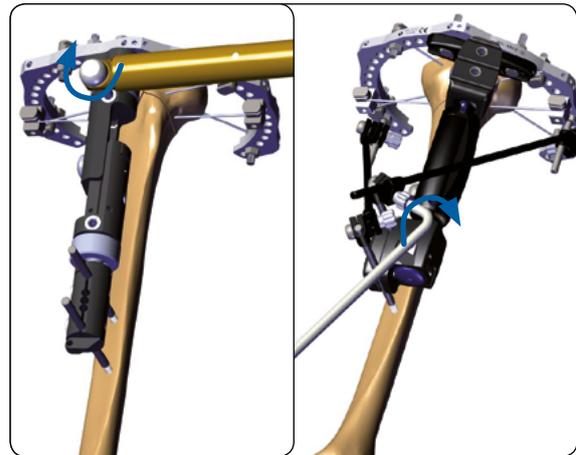


Fig. 10A

Fig. 10B

Bars Application

Two reinforcement bars should be added for stability, connecting the diaphyseal screws to the ring. Insert two 50mm posts into the ring and connect the bars by using the supplementary screw holder clamps. Connect the bars to the bone screw ends using two supplementary screw holder clamps (**Fig. 10B**).

POST OPERATIVE MANAGEMENT

Depending on fracture-type, and reduction as well as patient characteristics, active and passive mobilization may be commenced shortly after surgery. Patient is allowed initial toe-touch weight bearing. 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. Removal of the reinforcement bars is recommended when callus is first seen on X-ray, to increase load sharing at the fracture site.



PRECAUTION: Dynamization by loosening the micromovement locking nut and/or the central body locking nut of the monolateral fixator is not recommended in hybrid frames.



Fig. 11

MRI SAFETY INFORMATION

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

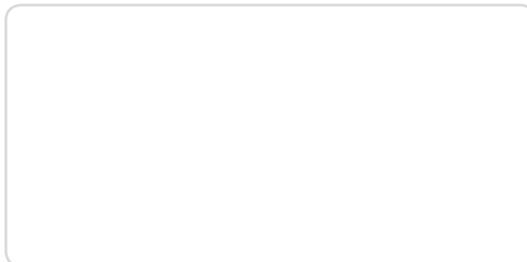
Electronic Instructions for use available at the website
<http://ifu.orthofix.it>

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

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