OPERATIVE TECHNIQUE

TrueLok™ EVO

Ring Fixation System

ORTHOFIX®
ORTHOPEDICS

TrueLok™ EVO

Ring Fixation System

Table of 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 kindly refer to the product IFU PQEVO, 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.

DESCRIPTION

The TrueLok™ EVO System (TL-EVO hereinafter) is a modular circular external fixation system based on Ilizarov principles.

The TL-EVO consists of external supports (rings and footplates), variable length struts and a variety of connection elements that build the external frame.

The external frame is connected to the bone by means of bone screws and wires.

Application and removal of the TL-EVO can be performed with Orthofix general orthopedic instrumentation.

The TL-EVO may be used in hybrid frames with the ProCallus™ Fixator, XCaliber™ Fixators, GALAXY FIXATION™ System and GALAXY FIXATION GEMINI™.

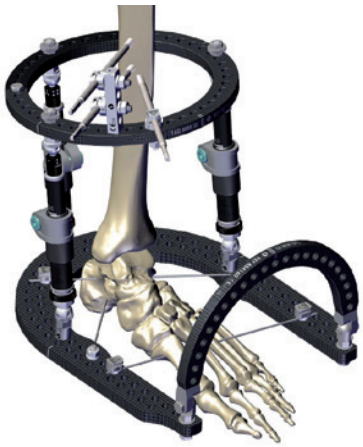
PROXIMAL TIBIA

DISTAL TIBIA

MIDSHAFT TIBIA

DISTAL FEMUR

FOOT AND ANKLE



FEATURES AND BENEFITS

Versatile, Stable, Simple
- Standardized operative technique
- Can be used as a tool in order to obtain the reduction of the bone fragments

Ease of use
- Radiolucent rings and struts provided also in pre-assembled frames
- TL-EVO is the first circular fixator on the market available in different folded pre-assembled frames, provided in sterile sets
- Dedicated sterile packaging and sterile sets, ready-to-use

MRI Conditional
- Rings and struts are made mainly of carbon fibers and they've been tested according to the ASTM F2503 Standard

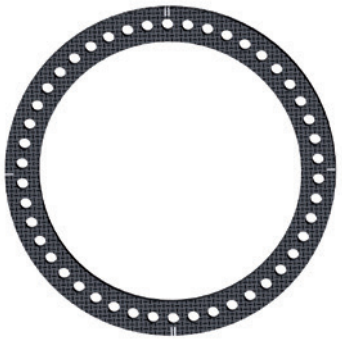
Dynamizable
- Dynamization integrated into the radiolucent adjust struts that can be unlocked at any time. It doesn't need additional components to obtain the dynamization

Radiolucent
- Rings and struts are in carbon fiber and their radiolucency allows for an easy visualization of the bone and the fracture site

TL-EVO EXTERNAL SUPPORTS

TL-EVO external supports are made from high-strength, Epoxy carbon fiber.

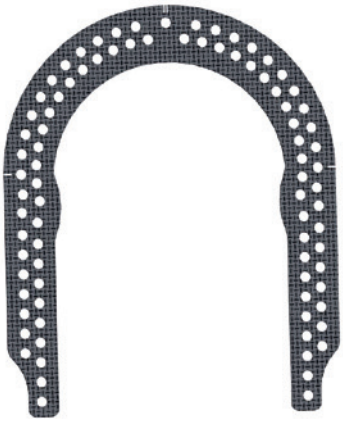
Full Rings
Full rings are the basic building blocks of the system. They are offered in 4 different sizes of internal diameters ranging from 140mm to 200mm. They have two sets of quadrant markings; conventionally anterior/posterior is a double line, medial/ lateral is a single line.



5/8 Rings
5/8 rings are offered in 4 sizes, ranging from 140mm to 200mm. These partial rings can be useful at the joints to extend the range of possible motion while the fixator is applied. 5/8 rings have two sets of quadrant markings, matching the markings found on full rings of the same diameter.

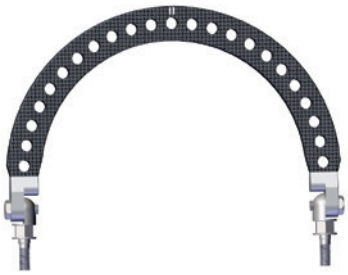
3/8 Rings
3/8 rings are offered in 4 sizes, ranging from 140mm to 200mm. These partial rings can be useful at the joints to extend the range of possible motion while the fixator is applied. 3/8 rings have one set of quadrant markings, matching the markings found on full rings of the same diameter.

Footplates
Footplates are modified rings with elongated ends. They are available in four sizes, ranging from 140mm to 200mm. The footplate has two sets of quadrant markings, matching the markings found on full rings of the same diameter.



Foot arches

Foot arches also come in 4 different sizes, ranging from 140mm to 200mm. They can be connected to the footplate using nut with washer. The foot arches have two hinges (one for each extremity) that give the possibility to allow an angulation range from 0° to 180°. The required angulation is fixed by tightening the locking bolt (already assembled to the hinge) by means of the standard 10mm hex key.



TL-EVO ASSEMBLY ELEMENTS

All TL-EVO assembly elements are made from MRI Conditional stainless steel. Threaded elements have a standard M6 thread and can be adjusted using a 10mm wrench.

TL-EVO BOLTS AND NUTS

Bolts

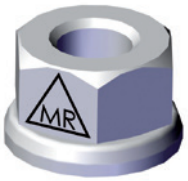
Bolts are offered in the standard bolt configuration as well as in the Speedbolt Configuration.

Bolt

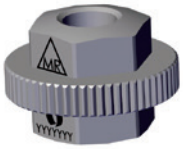
Speedbolt

Nuts

Nuts are offered in the standard nut with washer already assembled as well as in the Speednut Configuration.



Nut with washer



Speednut

TL-EVO FIXATION ELEMENTS

Wire Fixation Bolt
Wire fixation bolt functions as either a slotted wire fixation bolt or a cannulated wire fixation bolt. The 10mm bolt head is slotted and the bolt neck is cannulated to accept a 1.8mm or 1.5mm wire. An additional design feature is the horizontal grooves on the slot and the slotted washer, which enhance the gripping force on the wire. The washer prevents wire damage to the ring surface.

Wire Fixation Bolt

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

Half Pin Fixation Bolt

8mm Half Pin Fixation Bolt
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 shaft diameter. The 8mm half pin fixation bolt has a turnable collar that allows the insertion of a soft tissue protector. The specific design of the bolt minimizes the tension on the pins during tightening.

8mm Half Pin Fixation Bolt

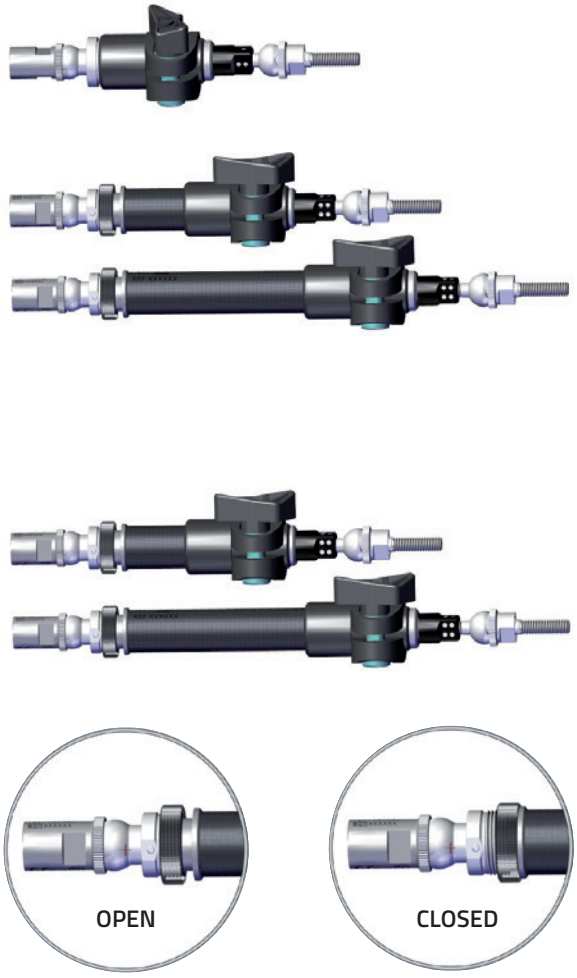
Hole Posts
Posts are available in three sizes, ranging from 2 to 4 holes. They have a 10mm by 13mm cross section, allowing the surgeon to stabilize them with a 10mm wrench. The posts have a standard female threaded base, allowing them to be secured to an external support by a bolt.

Hole Posts

TL-EVO STRUTS

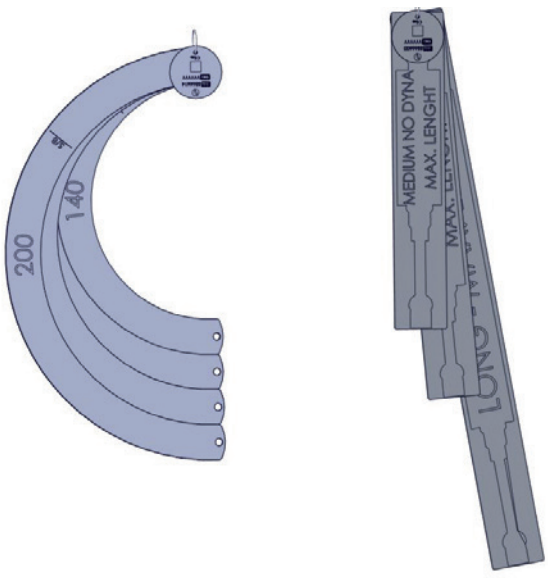
Struts are available in three sizes: medium static, medium with dynamizer, long with dynamizer. They have a lockable universal hinge on both ends that allows acute angular and rotational corrections. The body of the strut consists of two telescoping carbon fiber tubes, an outer tube and an inner tube, which can be locked together at various lengths using the manual wing bolt and central locking bolt, thus allowing acute length adjustment. The inner tube is attached to a square-sided plastic bushing. The plastic bushing mates with the threaded rod in a manner such that the rod moves relative to the carbon fiber 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. To provide distraction, turn the bushing in the direction of increasing numbers. To provide compression, turn the bushing in the direction of decreasing numbers.

The outer tube of "medium/long strut with dyna" integrates a dynamization module. The dynamization module can be used to dynamize an existing frame towards the end of treatment or at any stage where dynamization of the fracture callus or regenerate is required. The dynamization is activated when the integrated dynamization module of the strut is in the open position. The dynamization is locked when the dynamization module of the strut is in the closed position. It is possible to switch from closed to open configuration (and vice versa) by means of the adjustable ring.



TL-EVO STRUT AND RING TEMPLATES

Proper strut and ring sizing are essential to prepare the external fixation frame for the treatment of the fracture as required. The surgeon must determine the proper strut and ring size required based on the size of the limb. Use of the TL-EVO templates provides a simple and reliable way to determine the proper strut and ring size.



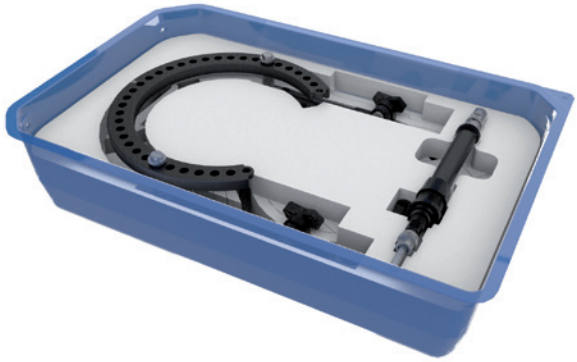
TL-EVO STERILE SET

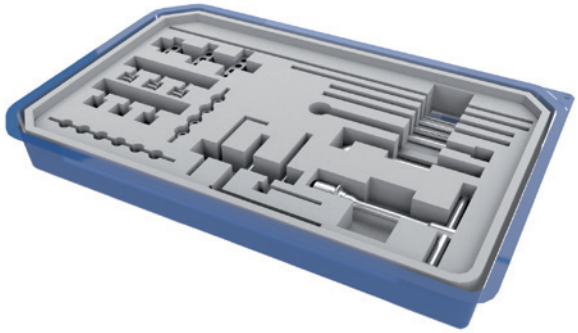
There are 2 types of TL-EVO sterile sets:

- Frame Sets
- Connection Element sets

A sterile Frame Set contains all required components to prepare an external fixation frame: rings and struts, with bolts and nuts. The basic frame (2 external supports and 2 struts) is already assembled into the set; the surgeon can further complete the frame with the third strut and add additional rings/strut strut if required.

A sterile Connection Element set is composed by all the fixation elements and minimum instrumentation to allow the frame fixation on the limb. There are 3 different versions of Connection Element set, depending on the bone fixation preference (HA coated bone screws, Cylindrical bone screws and K.wires).





EQUIPMENT

All TL-EVO elements are provided in sterile pack with the exception of TL-EVO templates (for rings and struts).

SIZING TEMPLATES

Part #	Description
886663	TRUELOK EVO RING AND STRUT TEMPLATES

EXTERNAL SUPPORTS

Part #	Description
	5/8 RINGS
99-882140	RX 5/8 MODULAR RING D 140MM STERILE
99-882160	RX 5/8 MODULAR RING D 160MM STERILE
99-882180	RX 5/8 MODULAR RING D 180MM STERILE
99-882200	RX 5/8 MODULAR RING D 200MM STERILE
	3/8 RINGS
99-881140	RX 3/8 MODULAR RING D 140MM STERILE
99-881160	RX 3/8 MODULAR RING D 160MM STERILE
99-881180	RX 3/8 MODULAR RING D 180MM STERILE
99-881200	RX 3/8 MODULAR RING D 200MM STERILE
	FULL RINGS
99-880140	RX FULL RING D 140MM STERILE
99-880160	RX FULL RING D 160MM STERILE
99-880180	RX FULL RING D 180MM STERILE
99-880200	RX FULL RING D 200MM STERILE
	FOOTPLATE
99-883140	RX FOOTPLATE D 140MM STERILE
99-883160	RX FOOTPLATE D 160MM STERILE
99-883180	RX FOOTPLATE D 180MM STERILE
99-883200	RX FOOTPLATE D 200MM STERILE
	FOOT ARCHES
99-884140	RX FOOT ARCH D 140MM STERILE
99-884160	RX FOOT ARCH D 160MM STERILE
99-884180	RX FOOT ARCH D 180MM STERILE
99-884200	RX FOOT ARCH D 200MM STERILE

STRUTS

Part #	Description
99-886005	TRUELOK EVO RX STRUT LONG WITH DYNA STERILE
99-886004	TRUELOK EVO RX STRUT MEDIUM WITH DYNA STERILE
99-886006	TRUELOK EVO RX STRUT MEDIUM STATIC STERILE

CONNECTION ELEMENTS

Part #	Description
99-885000M	TLEVO NUT WITH WASHER PACK OF 5 STERILE
99-885001M	TLEVO WIRE FIXATION BOLT PACK OF 4 STERILE
99-885003M	TLEVO BOLT PACK OF 4 L 16.5MM STERILE
99-885007M	TLEVO HALF PIN FIXATION BOLT PACK OF 4 STERILE
99-885002M	TLEVO 8MM HALF PIN FIXATION BOLT PACK OF 4 STERILE
99-885008M	TLEVO SPEED NUT PACK OF 2 STERILE
99-885009M	TLEVO SPEED BOLT PACK OF 2 STERILE
99-885004	TLEVO 2 HOLES POST STERILE
99-885005	TLEVO 3 HOLES POST STERILE
99-885006	TLEVO 4 HOLES POST STERILE

The TL PLUS Wire Tensioner (54-1139) has to be ordered separately

PRE-ASSEMBLED FRAME SETS*

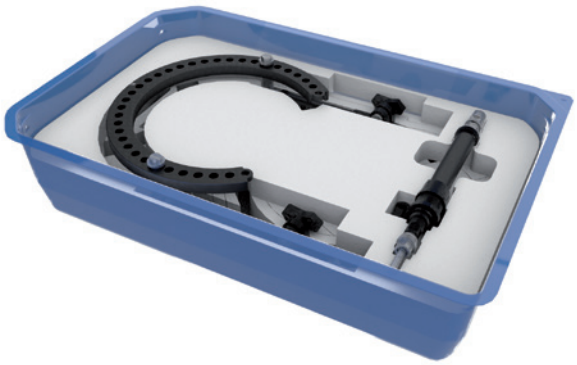
Part #	Description
99-88001	TRUELOK EVO SET RX RINGS D 160MM RX STRUTS LONG STERILE
99-88002	TRUELOK EVO SET RX RINGS D 160MM RX STRUTS MEDIUM STERILE
99-88003	TRUELOK EVO SET RX RINGS D 180MM RX STRUTS LONG STERILE
99-88004	TRUELOK EVO SET RX RINGS D 180MM RX STRUTS MEDIUM STERILE
99-88005	TRUELOK EVO SET RX RINGS D 200MM RX STRUTS LONG STERILE
99-88006	TRUELOK EVO SET RX RINGS D 200MM RX STRUTS MEDIUM STERILE
99-88007	TRUELOK EVO SET RX FOOTPLATE WITH RING D 160MM RX STRUTS LONG STERILE
99-88008	TRUELOK EVO SET RX FOOTPLATE WITH RING D 180MM RX STRUTS LONG STERILE

** Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Orthofix representative if you have questions about the availability of Orthofix products in your area.*

99-880XX TL-EVO double ring frame set sterile

Consisting of:

Description	Qty
RX 5/8 MODULAR RING DXXXMM	2
RX 3/8 MODULAR RING DXXXMM	1
TRUELOK EVO RX STRUT (LONG or MEDIUM) WITH DYNA	3
TLEVO SPEED NUT	3
TLEVO SPEED BOLT	3
TLEVO BOLT L16.5MM	2
TLEVO NUT WITH WASHER	2



99-8800X TL-EVO footplate frame set sterile

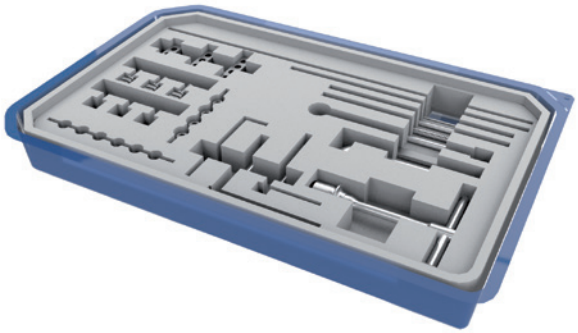
Consisting of:

Description	Qty
RX 5/8 MODULAR RING DXXXMM	1
RX FOOTPLATE DXXXMM	1
RX FOOT ARCH DXXXMM	1
RX 3/8 MODULAR RING DXXXMM	1
TRUELOK EVO RX STRUT LONG WITH DYNA	3
TLEVO SPEED NUT	3
TLEVO SPEED BOLT	3
TLEVO BOLT L16.5MM	2
TLEVO NUT WITH WASHER	4

CONNECTION ELEMENT SETS*

Part #	Description
99-88018	TRUELOK EVO CONNECTION ELEMENT CYLINDR PINS SET STERILE
99-88019	TRUELOK EVO CONNECTION ELEMENT CONICAL PINS SET STERILE
99-88020	TRUELOK EVO CONN ELEMENT K WIRES CYLINDR PINS SET STERILE

** Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Orthofix representative if you have questions about the availability of Orthofix products in your area.*



99-88018 TL-EVO Connection Element Cylindrical Pins Set Sterile

Consisting of:

Part #	Description	Qty
99-941640	XCALIBER CYLINDRICAL SCREW SHAFT D6MM THREAD 6MM L 180/40 QC	6
99-885002	TRUELOK EVO 8MM HALF PIN FIXATION BOLT	6
99-885003	TRUELOK EVO BOLT L16.5MM	6
99-885004	TRUELOK EVO 2 HOLES POST	2
99-885005	TRUELOK EVO 3 HOLES POST	2
99-885006	TRUELOK EVO 4 HOLES POST	2
99-885000	TRUELOK EVO NUT WITH WASHER	12
52-1020	TL HEX DRIVER 1/8''	1
54-1154	TL WRENCH COMBO 10MM	1
54-2226	TL 90 DEGREE TUBULAR WRENCH	1
93162	T-WRENCH HEXAGON 5-5 QC	1
11137	SCREW GUIDE L 80MM	1
11105	DRILL GUIDE D4.8MM L80MM	1
1-1100201	DRILL BIT D4.8MM L240MM TIN COATED - QC	1

99-88019 TL-EVO Connection Element Conical Pins Set Sterile

Consisting of:

Part #	Description	Qty
99-611540	XCALIBER OSTEOTITE CONICAL SCREW SHAFT D6mm THREAD D6.0-5.6MM L 150/40	6
99-885002	TRUELOK EVO 8MM HALF PIN FIXATION BOLT	6
99-885003	TRUELOK EVO BOLT L16.5MM	6
99-885004	TRUELOK EVO 2 HOLES POST	2
99-885005	TRUELOK EVO 3 HOLES POST	2
99-885006	TRUELOK EVO 4 HOLES POST	2
99-885000	TRUELOK EVO NUT WITH WASHER	12
52-1020	TL HEX DRIVER 1/8''	1
54-1154	TL WRENCH COMBO 10MM	1
54-2226	TL 90 DEGREE TUBULAR WRENCH	1
91150	UNIVERSAL T-WRENCH	1
11137	SCREW GUIDE L 80MM	1
11105	DRILL GUIDE D4.8MM L80MM	1
1-1100201	DRILL BIT D4.8MM L240MM TIN COATED - QC	1

99-88020 TL-EVO Connection Element K Wires and Cylindrical Pins Set Sterile

Consisting of:

Part #	Description	Qty
99-941640	XCALIBER CYLINDRICAL SCREW SHAFT D6MM THREAD 6MM L 180/40 QC (941640)	3
99-885002	TRUELOK EVO 8MM HALF PIN FIXATION BOLT	3
99-54-1216	TL WIRE BAYONET D1.8MM L400MM	3
99-885001	TRUELOK EVO WIRE FIXATION BOLT	6
99-885003	TRUELOK EVO BOLT L16.5MM	3
99-885004	TRUELOK EVO 2 HOLES POST	2
99-885005	TRUELOK EVO 3 HOLES POST	2
99-885006	TRUELOK EVO 4 HOLES POST	2
99-885000	TRUELOK EVO NUT WITH WASHER	12
52-1020	TL HEX DRIVER 1/8''	1
54-1154	TL WRENCH COMBO 10MM	1
54-2226	TL 90 DEGREE TUBULAR WRENCH	1
93162	T-WRENCH HEXAGON 5-5 QC	1
11137	SCREW GUIDE L 80MM	1
11105	DRILL GUIDE D4.8MM L80MM	1
1-1100201	DRILL BIT D4.8MM L240MM TIN COATED - QC	1

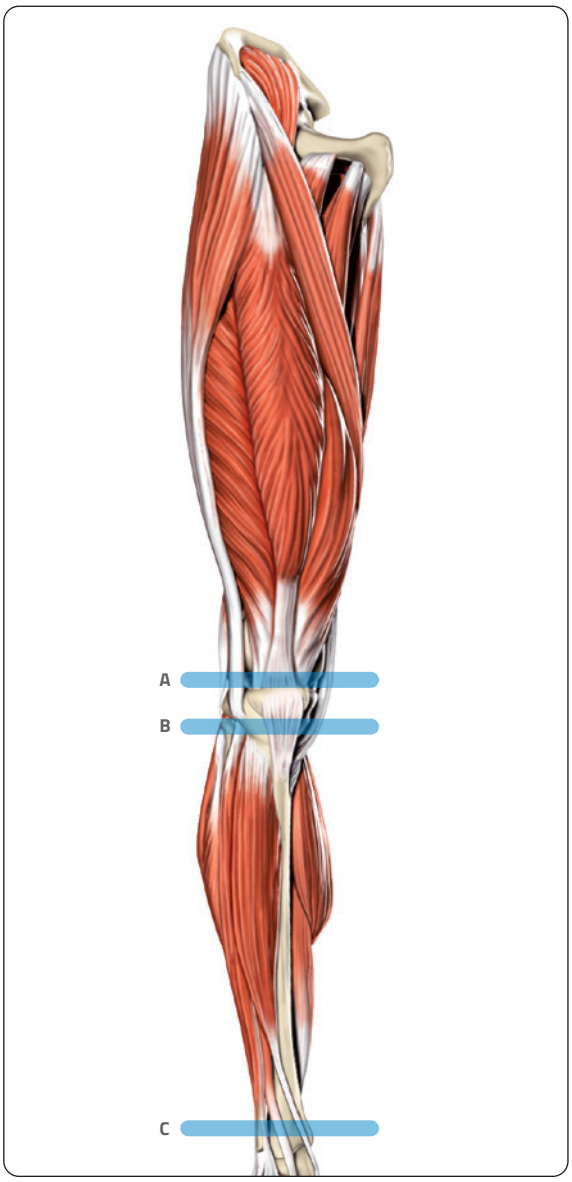
The TL PLUS Wire Tensioner (54-1139) has to be ordered separately.

TrueLok™ EVO 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.

PERIARTICULAR SAFE CORRIDORS

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

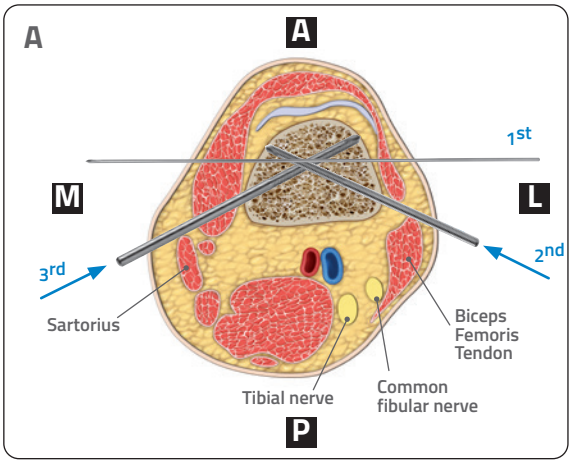
Precaution: Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the anatomical structures.



Distal Femur

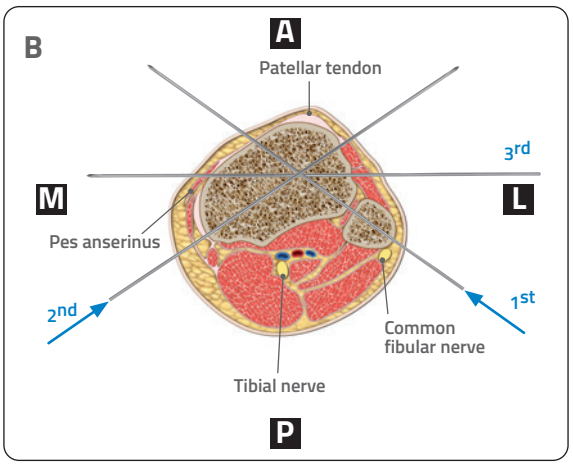
Wire and screw fixation in the distal femur is challenging due to the important periarticular structures present. Furthermore, narrow wire crossing angles produce instability in the sagittal plane. Correct wire and screw insertion is therefore crucial.

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.



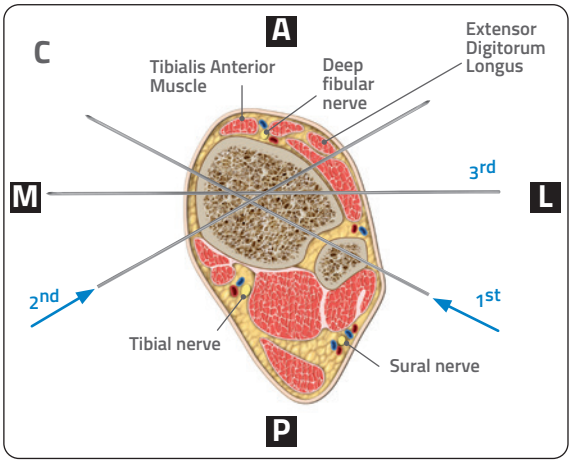
Proximal Tibia

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

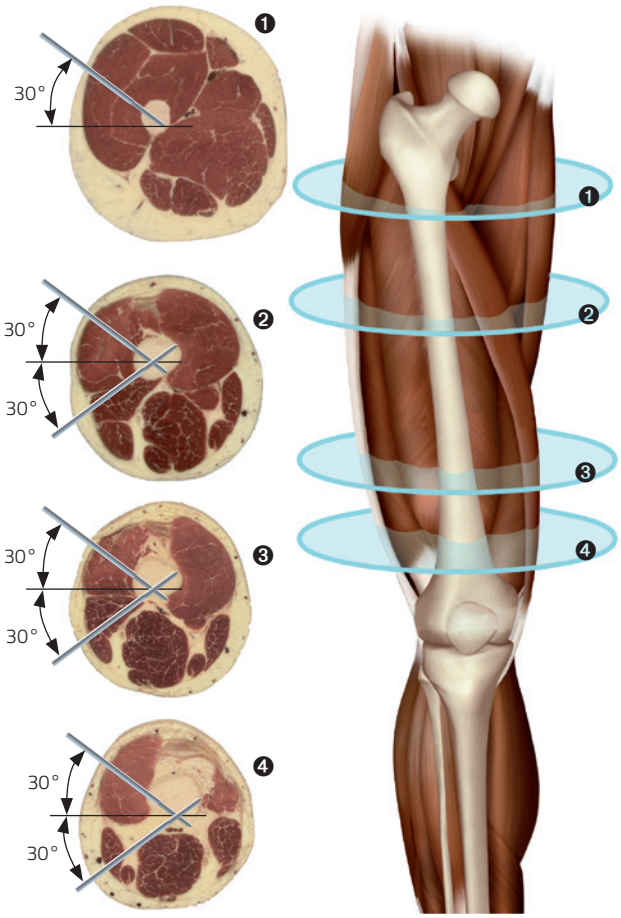
WARNING: During screw insertion, do not enter the joints or the growth plates in pediatric patients to avoid joint damage or growth impairment.

METAPHYSEAL AND DIAPHYSEAL SAFE CORRIDORS

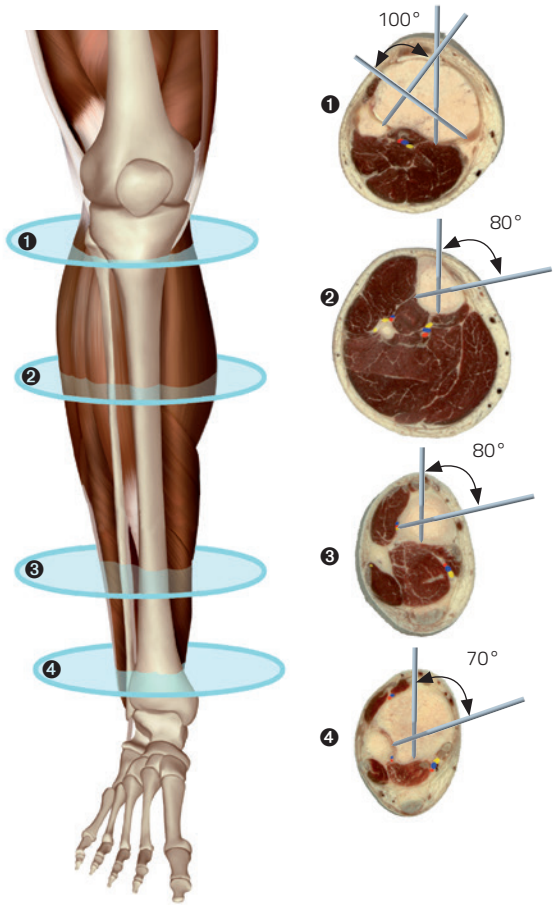
Lower Limb

The external fixation assemblies described in this manual are suggested configurations to achieve stability through the optimal use of components and efficiency in application. Each fixator configuration for each anatomical site can conveniently be linked to the adjacent region; this is the rationale for the choice of screw position and rod connections. In so doing, the surgeon can perform damage control stabilisation from pelvis to foot with familiarity of one fixator configuration for each anatomical region.

Femur
In the femur, screws can be inserted within an arc of 30 degrees on either side of the coronal plane, i.e. from 30 degrees postero-lateral to 30 degrees anterolateral.



Tibia
Screw insertion in the tibia is within the safe corridors illustrated in the cross-sections. The anteroposterior screw is inserted 1cm medial to the crest of the tibia; screw insertion through the crest carries the risk of thermal necrosis during drilling due to the thickness of this part of the tibia and is not recommended. Screws should not be inserted through the lateral side or anterior compartment except for the proximal one quarter (the tibia plateau and adjacent metaphyseal region).



SURGICAL PROCEDURE FOR TIBIAL PLATEAU FRACTURE

Part #	Description
886663	TRUELOK EVO RING AND STRUT TEMPLATES

Use the provided templates to choose the appropriate ring and strut sizes according to limb dimension **(Fig 1)**.

Precaution: When choosing two 5/8 rings, the openings should ideally be oriented in the same direction (i.e. both open anteriorly, posteriorly, medially). The surgeon must check the feasibility of the frame before applying it on the patient to ensure that struts will reach the appropriate holes on the rings and the position of the struts will not interfere with the soft tissue. If soft tissue interference has occurred, this can be mitigated by adding a 3/8 ring to the 5/8 ring and transforming the latter into a full ring. This procedure allows the surgeon to change the position of the struts and reduce the risk of soft tissue interference.

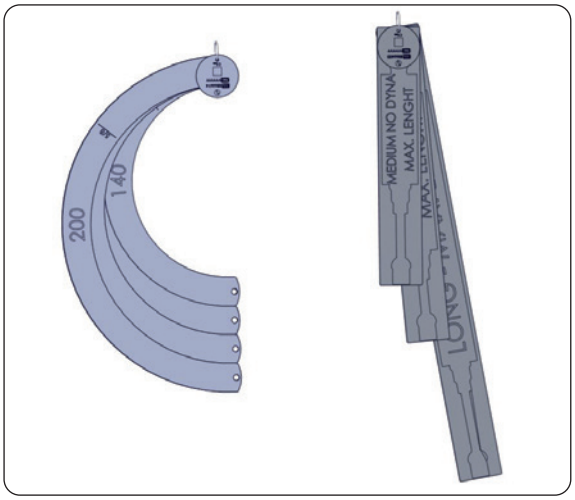


Fig. 1

Wire Insertion

Part #	Description
54-1154	TL WRENCH COMBO 10MM
54-2226	TL 90 DEGREE TUBULAR WRENCH

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

Refer to the safe corridors **(page 12)** for wire insertion. The sequence of wire insertion will vary depending on the fracture or specific nature of the disorder and the surgeon's preference.

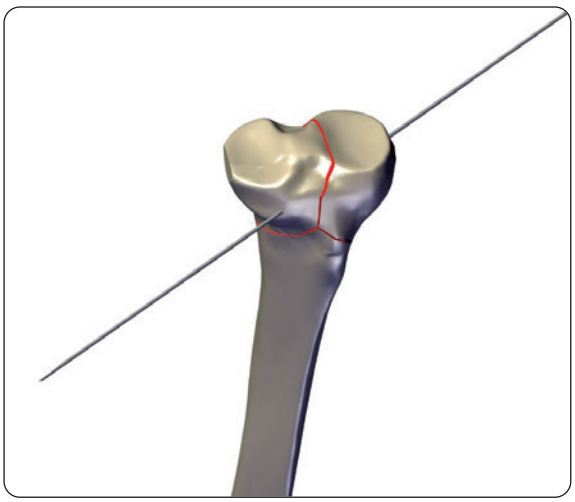


Fig. 2

For optimal stability three proximal tibial wires should be applied. The first wire can be inserted free-hand from postero-lateral to antero-medial **(Fig.2)**. It is possible to insert the wire through the head of the fibula or just anteriorly.

Optional: If needed, perform reduction with an olive wire. Compress the fracture line by pulling the wire gently with the tensioner under image intensifier. Stop when the fracture gap has closed.

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 perpendicular to the tibial anatomic axis **(Fig.3)**.

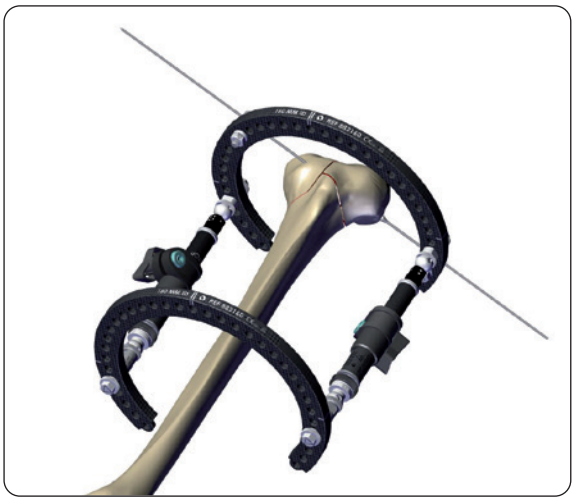


Fig. 3

Warning: Use only "TL-EVO wire fixation bolts" and "TL-EVO nuts with washer" when using TL-EVO rings in order to avoid ring surface damaging and subsequent loss of fixation.

Insert the second wire from postero-medial to anterolateral **(Fig 4)**.

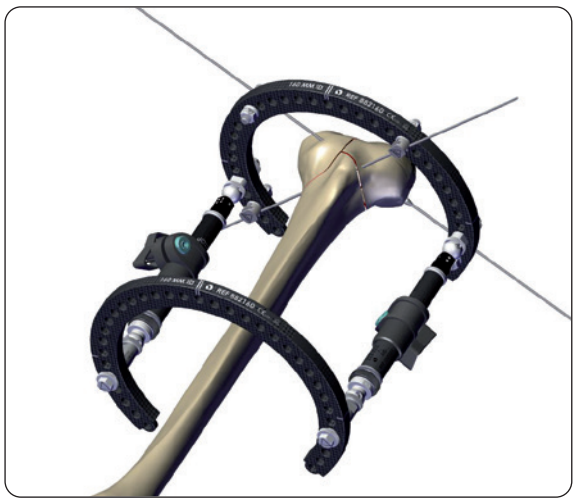


Fig. 4

Insert the third wire from lateral to medial **(Fig 5)**.

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

Precaution: If necessary, to avoid bending the wire, the space between the ring and the wire can be filled using a post, or remove the wire and reinsert in a different position.

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.

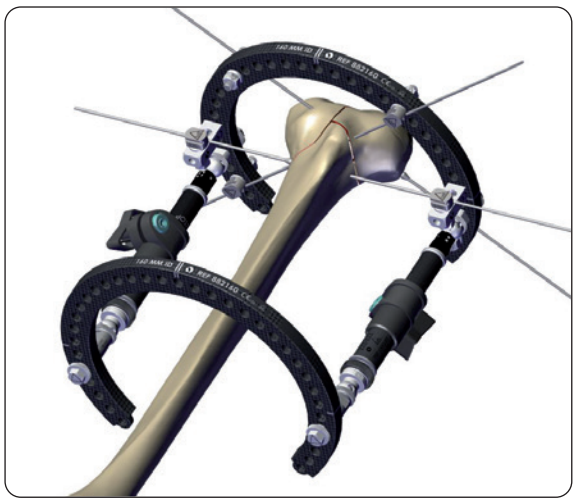


Fig. 5

Wire Tensioning

Part #	Description
54-1139	WIRE TENSIONER
54-1154	TL WRENCH COMBO 10MM
54-2226	TL 90 DEGREE TUBULAR WRENCH

Tension the first two wires simultaneously **(Fig.6)**. Tighten the nut with the 10mm Wrench, locking the wire fixation bolt present at the opposite side from the one where tensioner will be applied. Ensure the tensioner head captures the wire fixation bolt appropriately. Based on the characteristics of the patient and the fracture, tension the wires up to 130Kg; tighten the nut on the wire fixation bolt securely prior to releasing the tensioner. Tension the third wire in the same way. In case a wire with olive is used, tensioning must be performed from the side opposite the olive.

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.

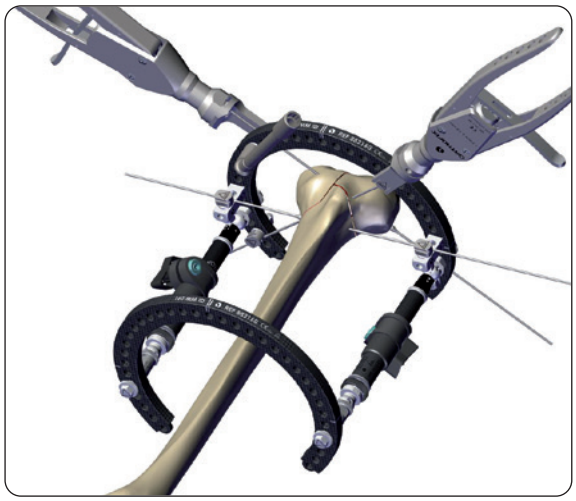


Fig. 6

Pin insertion

Part #	Description
11137	SCREW GUIDE L 80MM
11105	DRILL GUIDE D4.8MM L80MM
1-1100201	DRILL BIT D4.8MM L240MM TIN COATED - QC
93162	T-WRENCH HEXAGON 5-5 QC
	or
91150	UNIVERSAL T-WRENCH
54-1154	TL WRENCH COMBO 10MM
54-2226	TL 90 DEGREE TUBULAR WRENCH

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 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.

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

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 fixation bolt:

1. Select the desired position and through a small skin incision 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 the drill bit through the screw guide **(Fig.7a)**. Slightly tighten the nut on the half pin fixation bolt to keep desired orientation of the screw guide.
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.7b)**.
4. Untighten the nut, remove the screw guide, and turn the 8mm half pin collar until the appropriate number (representing the shaft diameter) is aligned directly below the half pin.
5. The half pin fixation bolt is then secured firmly to the external support with a nut using a 10mm Wrench **(Fig.8)**.

Optional: 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.

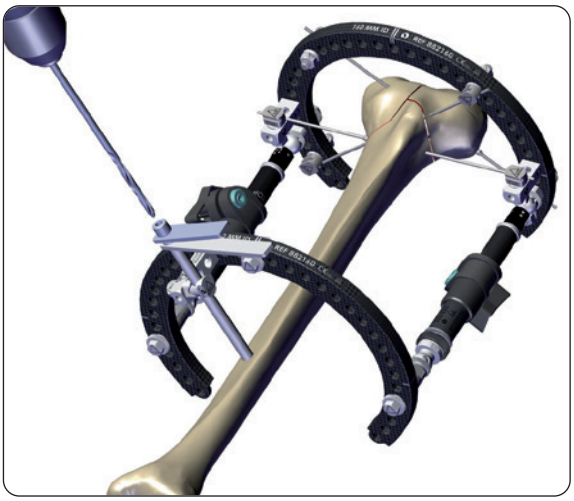


Fig. 7a

Fig. 7b

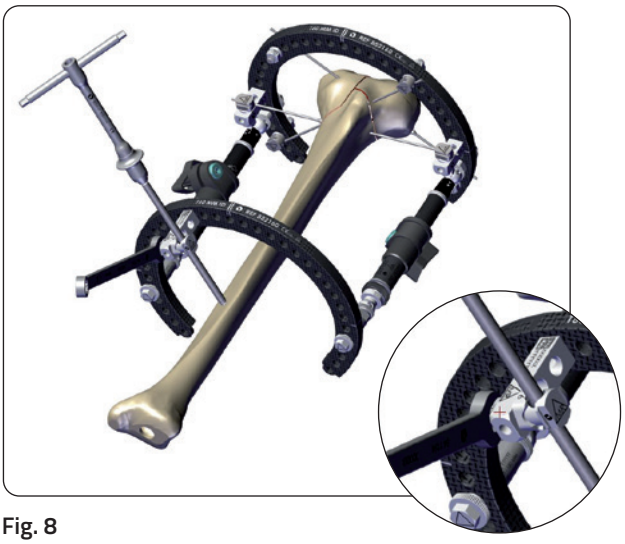


Fig. 8

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 of the ring and one on the distal, or spaced at a distance using a post) **(Fig.9)**. 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 post length 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 16.5mm 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. 9

Frame locking

Part #	Description
54-1154	TL WRENCH COMBO 10MM
54-2226	TL 90 DEGREE TUBULAR WRENCH
52-1020	TL HEX DRIVER 1/8"

After all the necessary half pins and wires have been inserted, manual reduction of the fracture is performed releasing the central wing bolt, the speed nut and the speed bolt on each strut. After achieving a satisfactory reduction, all the nuts and bolts have to be tightened **(Fig.10)**.

Tighten the central wingbolts only after having tightened speednuts and the speedbolts.

Add a third TL-EVO strut for definitive stabilization. A fourth strut can be added at surgeon's discretion.

Precaution: At least three struts should be used in each frame block when weightbearing.

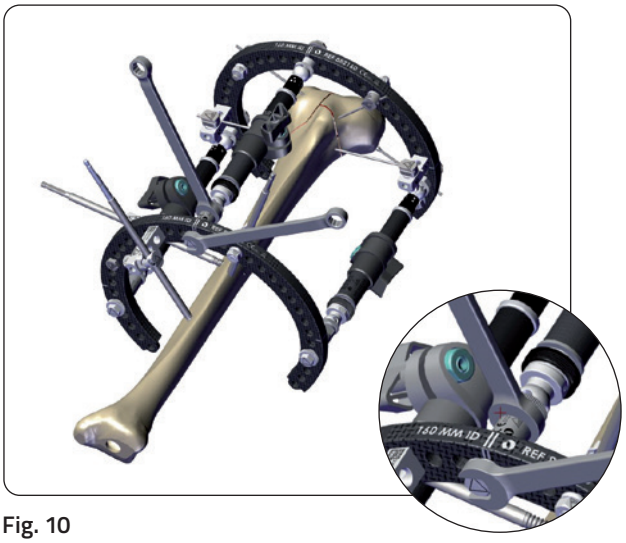


Fig. 10

After the manual closure, remove the wingbolts **(Fig.11)**. To achieve the definitive closure of the frame, lock the telescopic body of each strut by tightening the central locking bolt using an Allen Wrench 1/8" (e.g. TL Hex Driver) **(Fig.12)**.

Warning: Struts must be locked first manually by turning the hand lock clockwise before locking it firmly by tightening with the TL Hex Driver (52-1020) to avoid system collapse.

Warning: In the final frame, struts must not be locked with an angulation greater than 45°, to avoid ball joint failure and subsequent loss of fixation.

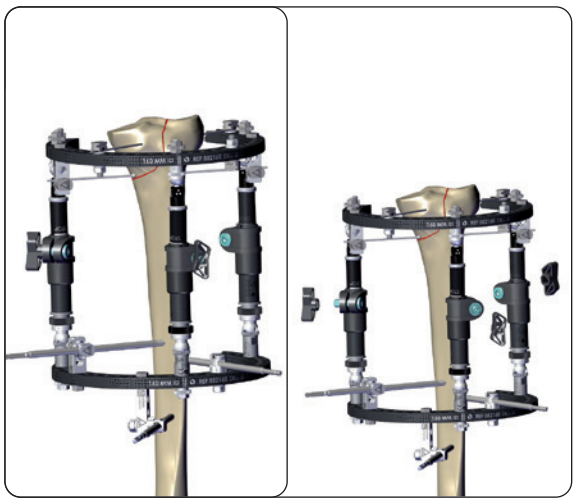


Fig. 11

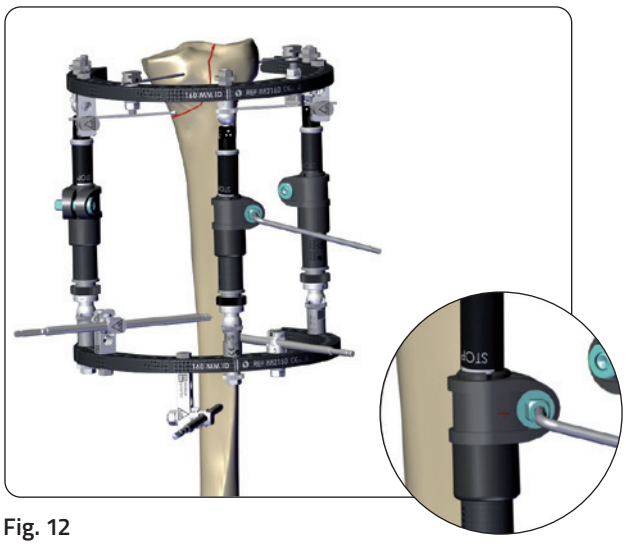


Fig. 12

A final gradual adjustment can be achieved by turning the plastic bushing of the struts by the desired amount, but only if the struts are parallel **(Fig.13)**.

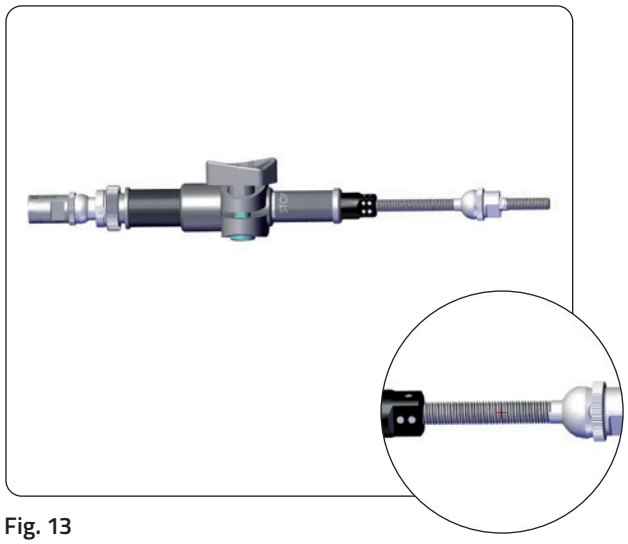


Fig. 13

Dynamization

Upon surgeon's discretion the frame can be dynamized by turning all of the black adjustable rings at the female end of each TL-EVO Strut to the open position **(Fig.14)**.

Warning: The HCP must check the position of the dynamization integrated module to avoid unexpected outcomes.

Warning: Do not use dynamization in applications that bridge a joint.

Precaution: The direction of dynamization is along the axis of the TL-EVO Struts: hence, carefully define their orientation based on the intended direction of dynamization.

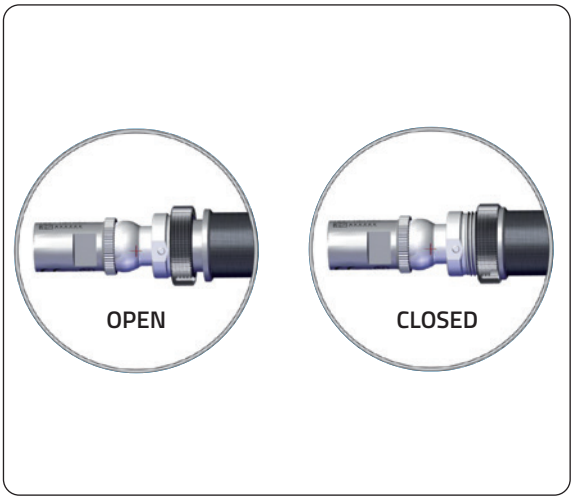


Fig. 14

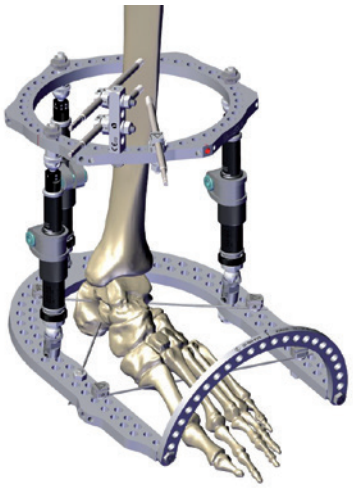
FRAME REMOVAL

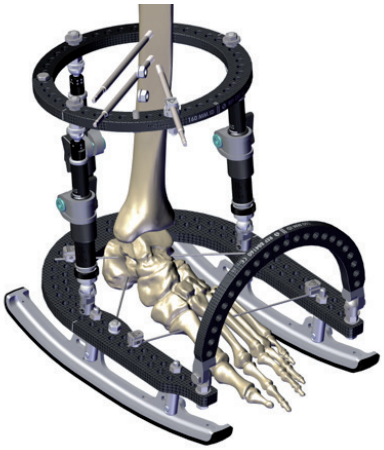
Part #	Description
93162 or 91150	T-WRENCH HEXAGON 5-5 QC or UNIVERSAL T-WRENCH
54-1154	TL WRENCH COMBO 10MM
54-2226	TL 90 DEGREE TUBULAR WRENCH

Untighten all halfpin bolts and/or wire fixation bolts using the appropriate wrenches (54-1154 or 54-2226). Remove the wires with the power drill. Remove bone screws with AO Quick Connection manually with the T-Wrench hexagon 5-5 QC (93162) or with a power drill. Remove bone screws that have been cut to length manually with the Universal T-Wrench (91150) or with a power drill. Remove the entire frame from the limb, if possible, or disassemble the frame untightening all the connection elements with the appropriate wrenches (54-1154 or 54-2226).

TRUELOK FAMILY COMBINED FRAME

The TL-EVO can be combined with some TL/TL-HEX Components to obtain the final construct. Here below are just some examples:





Please kindly refer to TL-2123-PL-E0 that contains information about the compatibility of TrueLok EVO components with TrueLok/TL-HEX components.

MRI (MAGNETIC RESONANCE IMAGING) SAFETY INFORMATION

If you are building a MRI conditional frame, the frame shall be accompanied by MRI Patient Cards. MRI Patient Cards are available for download at ifu.orthofix.it. It is the responsibility of the clinician to provide the MRI Patient Card to the patient.

 Outside the MRI bore MRI Safety Information. A person with the TL-EVO may be safely scanned under the following conditions. Failure to follow these conditions may result in serious injury. CAUTION: All TL-EVO components must be outside the bore to avoid risk of excessive RF heating.	
Device Name	TrueLok™ EVO
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	15 T/m or 1500 gauss/cm
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	First level Operating Mode
Maximum Whole-Body SAR	4 W/kg (first level control mode)
Maximum Head SAR	3.2 W/kg (first level control mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF with less than 2 degrees Celsius temperature rise
MR Image Artifact	The presence of this implant may produce an image artifact
Device Positioning	TL-EVO components must not extend into the MRI bore. Therefore, MR scanning of body parts where the TL-EVO is located is contraindicated

Non-clinical testing has demonstrated that the TL-EVO components are MR Conditional and are labeled MR CONDITIONAL "MR" according to the terminology specified in ASTM F2503 "Standard Practice for Marking Medical Devices and Other Items in the Magnetic Resonance Environment"

Displacement Information
The TL-EVO will not present an additional risk or hazard to a patient in the 1.5Tesla and 3Tesla MR environment with regard to translational attraction or migration and torque.

Heating Information
Comprehensive electromagnetic computer modeling and experimental testing was performed on the following systems:

- 1.5-Tesla/64-MHz: Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner.
- 3-Tesla/128-MHz: Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI, Active-shielded, horizontal field scanner to determine the worst heating in seven configurations of TL-EVO. From these studies, it is concluded that once the entire external fixation frame is visible outside the MR bore, the maximum heating is less than 4 °C.

Please note that temperature changes reported apply to the designed MR systems and characteristics used. If a different MR system is used, temperature changes may vary but are expected to be low enough for safe scanning as long as all TL-EVO components are placed outside the MR bore.

MR Patient Safety
MR in patients with TL-EVO can only be performed under these parameters. It is not allowed to scan the TL-EVO directly. Using other parameters, MRI could result in serious injury to the patient. When the TL-EVO is used in conjunction with other External Fixation Systems please be advised that this combination has not been tested in the MR environment and therefore higher heating and serious injury to the patient may occur. Because higher in vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan is required. Immediately abort the scan if the patient reports burning sensation or pain.

TL-EVO can only be guaranteed for MR when using the following components to build a frame:

TL-EVO Components

Part #	Description
99-885004	TRUELOK EVO 2 HOLES POST STERILE
99-885005	TRUELOK EVO 3 HOLES POST STERILE
99-885006	TRUELOK EVO 4 HOLES POST STERILE
99-882140	TRUELOK EVO RX 5/8 MODULAR RING D 140MM STERILE
99-882160	TRUELOK EVO RX 5/8 MODULAR RING D 160MM STERILE
99-882180	TRUELOK EVO RX 5/8 MODULAR RING D 180MM STERILE
99-882200	TRUELOK EVO RX 5/8 MODULAR RING D 200MM STERILE
99-881140	TRUELOK EVO RX 3/8 MODULAR RING D 140MM STERILE
99-881160	TRUELOK EVO RX 3/8 MODULAR RING D 160MM STERILE
99-881180	TRUELOK EVO RX 3/8 MODULAR RING D 180MM STERILE
99-881200	TRUELOK EVO RX 3/8 MODULAR RING D 200MM STERILE
99-880140	TRUELOK EVO RX FULL RING D 140MM STERILE
99-880160	TRUELOK EVO RX FULL RING D 160MM STERILE
99-880180	TRUELOK EVO RX FULL RING D 180MM STERILE
99-880200	TRUELOK EVO RX FULL RING D 200MM STERILE
99-883140	TRUELOK EVO RX FOOTPLATE D 140MM STERILE
99-883160	TRUELOK EVO RX FOOTPLATE D 160MM STERILE
99-883180	TRUELOK EVO RX FOOTPLATE D 180MM STERILE
99-883200	TRUELOK EVO RX FOOTPLATE D 200MM STERILE
99-884140	TRUELOK EVO RX FOOT ARCH D 140MM STERILE
99-884160	TRUELOK EVO RX FOOT ARCH D 160MM STERILE
99-884180	TRUELOK EVO RX FOOT ARCH D 180MM STERILE
99-884200	TRUELOK EVO RX FOOT ARCH D 200MM STERILE
99-886005	TRUELOK EVO RX STRUT LONG WITH DYNA STERILE
99-886004	TRUELOK EVO RX STRUT MEDIUM WITH DYNA STERILE
99-886006	TRUELOK EVO RX STRUT MEDIUM STATIC STERILE
99-88001	TRUELOK EVO SET RX RINGS D 160MM RX STRUTS LONG STERILE
99-88002	TRUELOK EVO SET RX RINGS D 160MM RX STRUTS MEDIUM STERILE
99-88003	TRUELOK EVO SET RX RINGS D 180MM RX STRUTS LONG STERILE
99-88004	TRUELOK EVO SET RX RINGS D 180MM RX STRUTS MEDIUM STERILE
99-88005	TRUELOK EVO SET RX RINGS D 200MM RX STRUTS LONG STERILE
99-88006	TRUELOK EVO SET RX RINGS D 200MM RX STRUTS MEDIUM STERILE
99-88007	TRUELOK EVO SET RX FOOTPLATE WITH RING D 160MM RX STRUTS LONG STERILE
99-88008	TRUELOK EVO SET RX FOOTPLATE WITH RING D 180MM RX STRUTS LONG STERILE
99-88017	TRUELOK EVO SET RX FOOTPLATE WITH RING D 200MM RX STRUTS LONG STERILE
99-885000	TRUELOK EVO NUT WITH WASHER STERILE
99-885001	TRUELOK EVO WIRE FIXATION BOLT STERILE
99-885003	TRUELOK EVO BOLT L 16.5MM STERILE
99-885007	TRUELOK EVO HALF PIN FIXATION BOLT STERILE
99-885008	TRUELOK EVO SPEEDNUT STERILE

TL-EVO Components

Part #	Description
99-885009	TRUELOK EVO SPEEDBOLT STERILE
99-885002	TRUELOK EVO 8MM HALF PIN FIXATION BOLT STERILE
99-885000M	TRUELOK EVO NUT WITH WASHER PACK OF 5 STERILE
99-885001M	TRUELOK EVO WIRE FIXATION BOLT PACK OF 4 STERILE
99-885003M	TRUELOK EVO BOLT L 16.5MM PACK OF 4 STERILE
99-885007M	TRUELOK EVO HALF PIN FIXATION BOLT PACK OF 4 STERILE
99-885002M	TRUELOK EVO 8MM HALF PIN FIX BOLT PACK OF 4 STERILE
99-885008M	TRUELOK EVO SPEEDNUT PACK OF 2 STERILE
99-885009M	TRUELOK EVO SPEEDBOLT PACK OF 2 STERILE

Self-drilling XCaliber Screws

Part #	Description
911530*	XCALIBER BONE SCREW L 150/30MM THREAD D 6.0-5.6MM
911540*	XCALIBER BONE SCREW L 150/40MM THREAD D 6.0-5.6MM
911550*	XCALIBER BONE SCREW L 150/50MM THREAD D 6.0-5.6MM
911560*	XCALIBER BONE SCREW L 150/60MM THREAD D 6.0-5.6MM
911570*	XCALIBER BONE SCREW L 150/70MM THREAD D 6.0-5.6MM
911580*	XCALIBER BONE SCREW L 150/80MM THREAD D 6.0-5.6MM
911590*	XCALIBER BONE SCREW L 150/90MM THREAD D 6.0-5.6MM
912630*	XCALIBER BONE SCREW L 260/30MM THREAD D 6.0-5.6MM
912640*	XCALIBER BONE SCREW L 260/40MM THREAD D 6.0-5.6MM
912650*	XCALIBER BONE SCREW L 260/50MM THREAD D 6.0-5.6MM
912660*	XCALIBER BONE SCREW L 260/60MM THREAD D 6.0-5.6MM
912670*	XCALIBER BONE SCREW L 260/70MM THREAD D 6.0-5.6MM
912680*	XCALIBER BONE SCREW L 260/80MM THREAD D 6.0-5.6MM
912690*	XCALIBER BONE SCREW L 260/90MM THREAD D 6.0-5.6MM
941625*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/25MM D 6/6MM QC
941630*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 180/30 QC
941635*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/35MM D 6/6MM QC
941640*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 180/40 QC
941645*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/45MM D 6/6MM QC
941650*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 180/50 QC

Self-drilling XCaliber Screws

Part #	Description
941660*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 180/60 QC
941670*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 180/70 QC
941680*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 180/80 QC
941690*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 180/90 QC
942625*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 260/25MM D 6/6MM QC
942630*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 260/30 QC
942635*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 260/35MM D 6/6MM QC
942640*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 260/40 QC
942645*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 260/45MM D 6/6MM QC
942650*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 260/50 QC
942660*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 260/60 QC
942670*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 260/70 QC
942680*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 260/80 QC
942690*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 6MM L 260/90 QC
941525*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/25MM D 6/5MM QC
941530*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/30MM D 6/5MM QC
941535*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/35MM D 6/5MM QC
941540*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 180/40 QC
941545*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/45MM D 6/5MM QC
941550*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 180/50 QC
941560*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 180/60 QC
941570*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 180/70MM D 6/5MM QC
942525*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 260/25MM D 6/5MM QC
942530*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 260/30MM D 6/5MM QC
942535*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 260/35MM D 6/5MM QC
942540*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 260/40 QC
942545*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 260/45MM D 6/5MM QC
942550*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 260/50 QC
942560*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 260/60 QC
942570*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 260/70 QC
942580*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 260/80 QC

Self-drilling XCaliber Screws

Part #	Description
942590*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 260/90 QC
943540*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 220/40 QC
943550*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 220/50 QC
943560*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 220/60 QC
943570*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 220/70 QC
944530*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 150/30 QC
944535*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 150/35 QC
944540*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 150/40 QC
944550*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 150/50 QC
945530*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 120/30 QC
945535*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 120/35 QC
945540*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 5MM L 120/40 QC
945420*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 4MM L 150/20 QC
945425*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 150/25MM D 6/4MM QC
945430*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 4MM L 150/30 QC
945435*	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 150/35MM D 6/4MM QC
945440*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 4MM L 150/40 QC
946420*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 4MM L 180/20 QC
946430*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 4MM L 180/30 QC
946440*	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6MM THREAD 4MM L 180/40 QC

** the products are listed in non-sterile configuration. Please consider that the same MRI information and performance are applicable to the same components in sterile configuration if available (code number preceded by 99- , e.g. 99-911530)*

XCaliber Osteotite Bone Screws

Part #	Description
99-611530	XCALIBER OSTEOTITE SCREW L 150/30MM THREAD D 6.0-5.6MM
99-611540	XCALIBER OSTEOTITE SCREW L 150/40MM THREAD D 6.0-5.6MM
99-611550	XCALIBER OSTEOTITE SCREW L 150/50MM THREAD D 6.0-5.6MM
99-611560	XCALIBER OSTEOTITE SCREW L 150/60MM THREAD D 6.0-5.6MM
99-611570	XCALIBER OSTEOTITE SCREW L 150/70MM THREAD D 6.0-5.6MM
99-611580	XCALIBER OSTEOTITE SCREW L 150/80MM THREAD D 6.0-5.6MM
99-611590	XCALIBER OSTEOTITE SCREW L 150/90MM THREAD D 6.0-5.6MM
99-612630	XCALIBER OSTEOTITE SCREW L 260/30MM THREAD D 6.0-5.6MM
99-612640	XCALIBER OSTEOTITE SCREW L 260/40MM THREAD D 6.0-5.6MM
99-612650	XCALIBER OSTEOTITE SCREW L 260/50MM THREAD D 6.0-5.6MM
99-612660	XCALIBER OSTEOTITE SCREW L 260/60MM THREAD D 6.0-5.6MM
99-612670	XCALIBER OSTEOTITE SCREW L 260/70MM THREAD D 6.0-5.6MM
99-612680	XCALIBER OSTEOTITE SCREW L 260/80MM THREAD D 6.0-5.6MM
99-612690	XCALIBER OSTEOTITE SCREW L 260/90MM THREAD D 6.0-5.6MM

X-Wire D1.8MM

Part #	Description
80131	X-WIRE WITH CENTRAL OLIVE DIAMETER 1.8MM L 400MM
80132	X-WIRE WITHOUT OLIVE DIAMETER 1.8MM L 400MM
99-80131	X-WIRE WITH CENTRAL OLIVE STERILE DIAMETER 1.8MM L 400MM
99-80132	X-WIRE WITHOUT OLIVE STERILE DIAMETER 1,8MM L 400MM

Bayonet Wire D1.8MM

Part #	Description
54-1215	TL,WIRE, W/STOPPER, 1.8MM X 400MM
54-1216	TL,WIRE, BAYONET, 1.8MM X 400MM
99-54-1215	TL,WIRE, W/STOPPER, 1.8MM X 400MM STERILE
99-54-1216	TL,WIRE, BAYONET, 1.8MM X 400MM STERILE

TL-EVO PROCALLUS™/XCALIBER™ Hybrid System

The TL-EVO PROCALLUS/XCALIBER 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-EVO PROCALLUS/XCALIBER Hybrid System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

TL-HEX SET

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

The following components can be used to build a frame in case of TL-HEX SET:

Part #	Description
99-88009	TL-HEX SET RINGS D160MM RX STRUTS LONG STERILE
99-88010	TL-HEX SET RINGS D160MM RX STRUTS MEDIUM STERILE
99-88011	TL-HEX SET RINGS D180MM RX STRUTS LONG STERILE
99-88012	TL-HEX SET RINGS D180MM RX STRUTS MEDIUM STERILE
99-88013	TL-HEX SET RINGS D200MM RX STRUTS LONG STERILE
99-88014	TL-HEX SET RINGS D200MM RX STRUTS MEDIUM STERILE
99-88015	TL-HEX SET FOOTPLATE WITH RING D160MM RX STRUTS LONG STERILE
99-88016	TL-HEX SET FOOTPLATE WITH RING D180MM RX STRUTS LONG STERILE

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

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

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

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

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

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

Rx Only

CE 0123

Distributed by:

orthofix.com

TL-2113-OPT-E0 C 12/24 (0425768)

ORTHOFIX® ORTHOPEDICS