

OPERATIVE TECHNIQUE

TrueLok™ EVO

Ring Fixation System

TrueLok™ EVO Galaxy Fixation Gemini™ Hybrid System



TrueLok™ EVO

Ring Fixation System

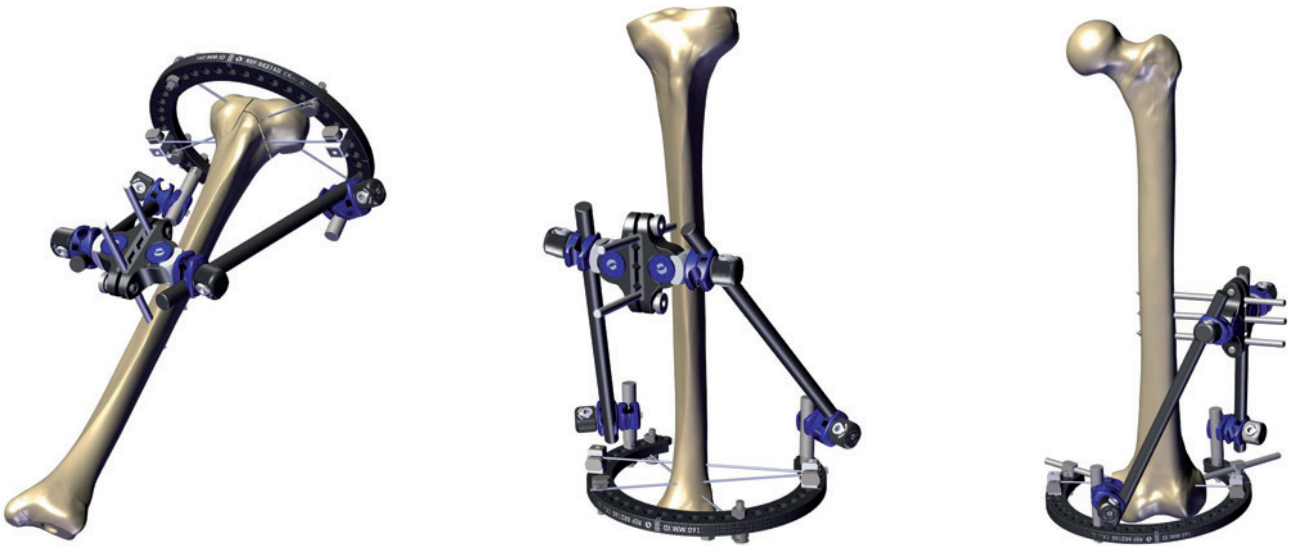
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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each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

INTRODUCTION

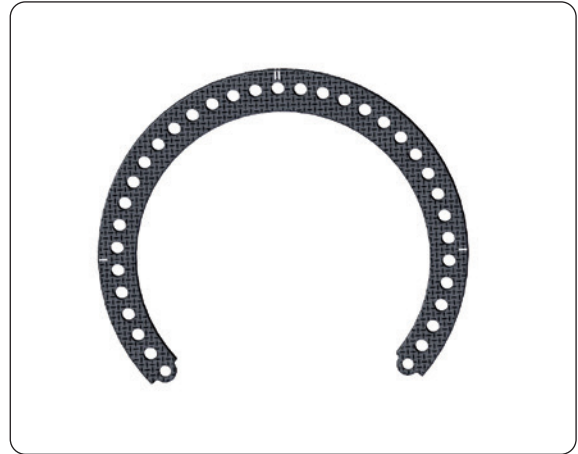
A Hybrid Fixator provides stability by combining the advantages of tensioned wires and cortical screws. This document describes the application of a Hybrid Fixator on the proximal tibia, but the concept can be also applied on metaphyseal and articular fractures in the distal tibia and the distal femur.



TL-EVO EXTERNAL SUPPORTS

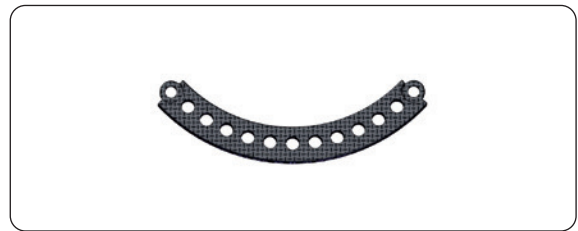
5/8 Rings

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.



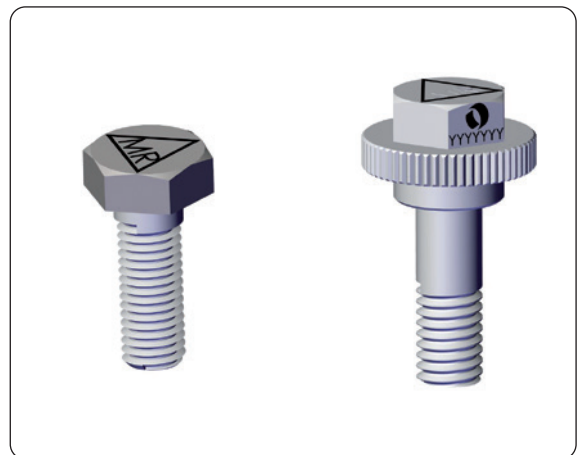
TL-EVO ASSEMBLY ELEMENTS

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.

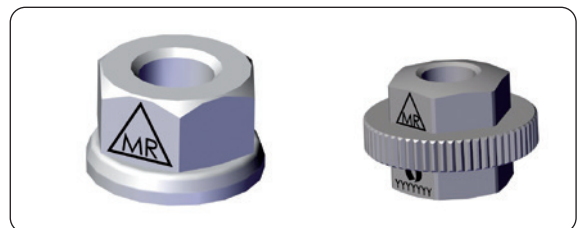


Bolt

Speedbolt

Nuts

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



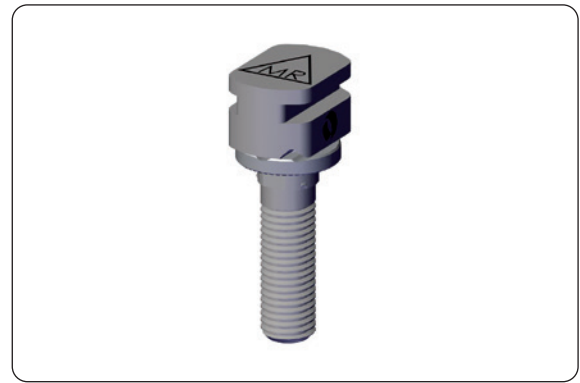
Nut with washer

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. The horizontal grooves on the slot and the slotted washer 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 diameters. 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

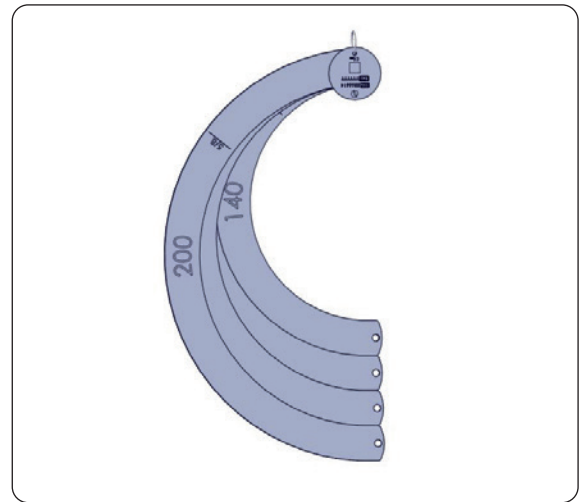
Posts are available in three sizes, ranging from 2 to 4 holes. They have a 10mm by 13mm cross section, allowing the surgeon to stabilize them with a 10mm wrench. The posts have a standard female threaded base, allowing them to be secured to an external support by a bolt.



Hole Posts

TL-EVO RING TEMPLATES

Proper ring sizing is essential to prepare the external fixation frame for the treatment of the fracture as required. The surgeon must determine the proper 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 ring size.



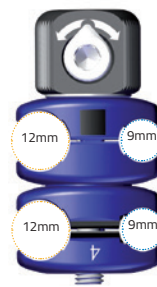
GALAXY FIXATION GEMINI™ COMPONENTS

Galaxy Fixation Gemini
UNIVERSAL SINGLE CLAMP (94100) 



Single clamps can hold 6-9-12mm diameters of rod and 4-6mm diameters of bone screw shaft.

ROD SEAT

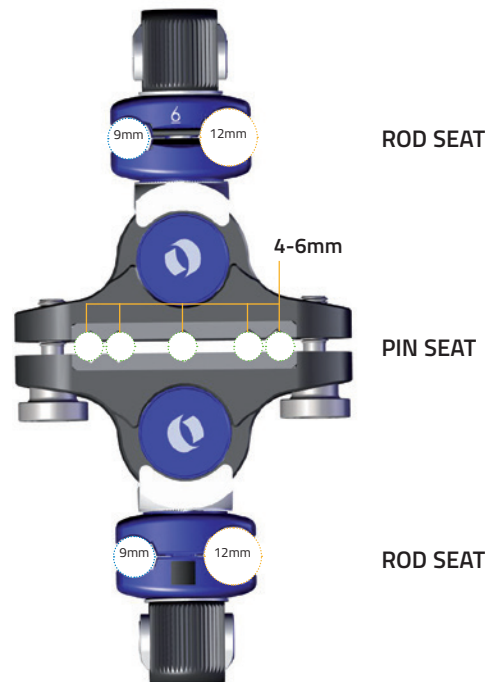


PIN SEAT



Markers on clamp slots: Easy identification of rod and pin diameter for each clamp slot.

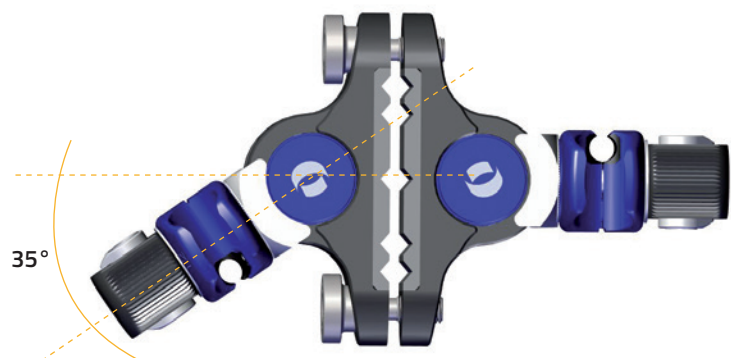




Multipin clamps can hold 9-12mm diameters of rod.
In multiscrew clamps insert minimum two screws in the most external seats, if possible, to increase frame stability.

Markers on clamp slots: Easy identification of rod and pin diameter for each clamp slot.

ANGULATION



Universal clamps are provided in non-sterile configuration only. Please refer to "Equipment Suggested" for detailed information.

Galaxy TL-HEX Connecting Post

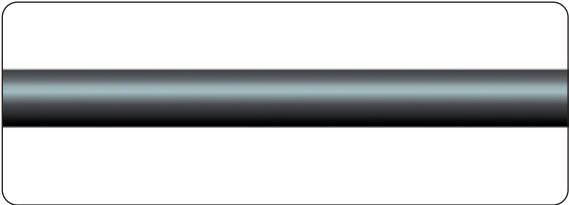
(93031) Galaxy TL-HEX Connecting Post
L50mm D12mm



(93032) Galaxy TL-HEX Connecting Post
L100mm D12mm



Rod Diameter 9,12mm (939XXX, 932XXX)



EQUIPMENT SUGGESTED

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

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 D140mm Sterile
99-882160	Rx 5/8 Modular Ring D160mm Sterile
99-882180	Rx 5/8 Modular Ring D180mm Sterile
99-882200	Rx 5/8 Modular Ring D200mm Sterile
3/8 RINGS	
99-881140	Rx 3/8 Modular Ring D140mm Sterile
99-881160	Rx 3/8 Modular Ring D160mm Sterile
99-881180	Rx 3/8 Modular Ring D180mm Sterile
99-881200	Rx 3/8 Modular Ring D200mm Sterile

ADDITIONAL COMPONENTS

Part #	Description	Qty
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
91150	Universal T-Wrench	1
54-2226	TL, 90 Degree Tubular Wrench	1
54-1139	TL PLUS Wire Tensioner With Tip	2
11103	Screw Guide, L100mm	3
1100201	Drill Bit Ø 4.8mm L240mm	1
11004	Trocar	1
30017	Allen Wrench 5mm	1
1100101	Drill Bit Ø 4.8mm L180mm	1
11105	Drill guide Ø 4.8mm L80mm	1

GALAXY FIXATION GEMINI

Part #	Description	Qty
94100	Universal Single Clamp	3
94200	Double Universal Multipin Clamp	1
93031	Galaxy TL-HEX Connecting Post L50mm D12mm	3
or		
93032	Galaxy TL-HEX Connecting Post L100mm D12mm	3

The TrueLok™ EVO Galaxy Fixation Gemini™ 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.

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 L16.5mm 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

RODS

Part #	Description	Qty
12mm RODS		
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
9mm RODS		
939100	Rod 100mm long	2
939150	Rod 150mm long	2
939200	Rod 200mm long	2
939250	Rod 250mm long	2
939300	Rod 300mm long	2

*Special order only

All rods are also available single- packed sterile. They can be ordered using the above code numbers preceded by 99- (e.g. 99-932100)

BONE SCREWS (Sterile)

Part #	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

KIRSCHNER WIRES (Sterile)

Part #	Description
99-54-1215	TL, Wire, W/Stopper, 1.8mm x 400mm
99-54-1216	TL, Wire, Bayonet, 1.8mm x 400mm

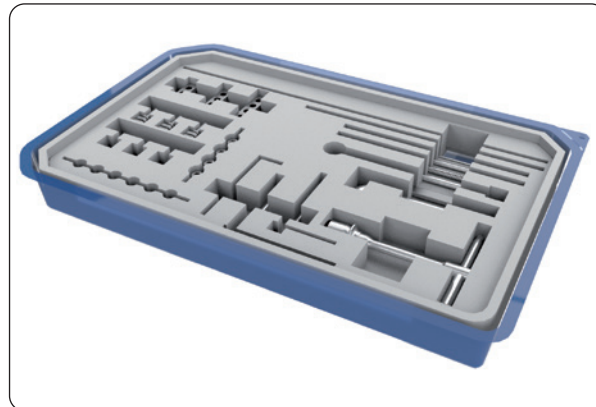
Alternative to the connection elements, additional components, bone screws and Kirschner Wire Tables, the TL-EVO connection element set code 99-88020 can be used.

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

* 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.



XCALIBER™ HYBRID SYSTEM SURGICAL PROCEDURE TL-EVO RING APPLICATION

SAFE CORRIDORS

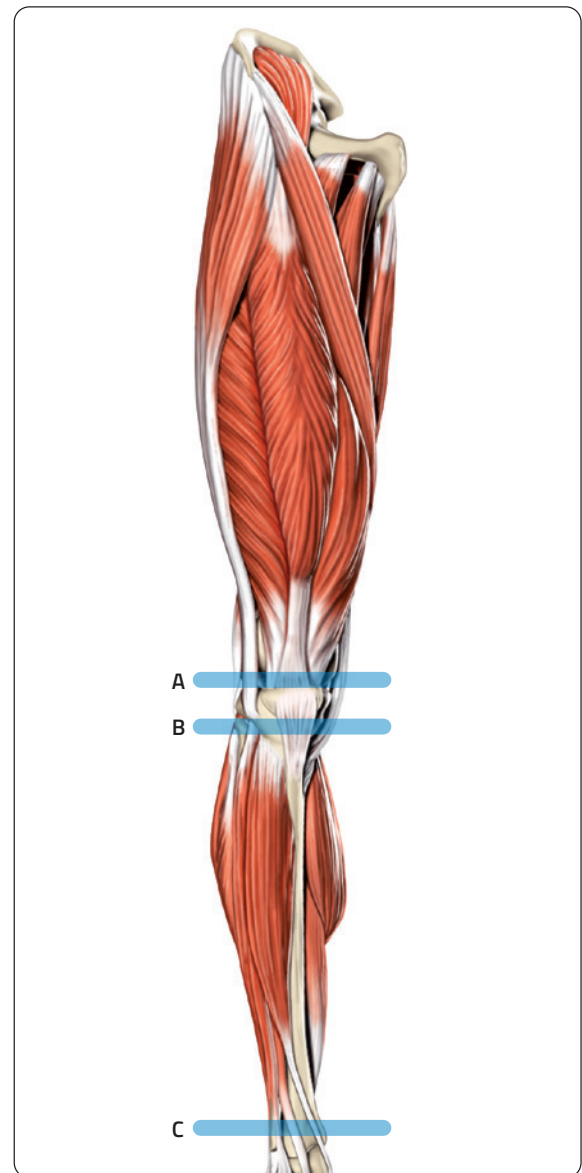
In figures A, B and C safe corridors for the insertion of the fixation elements are represented.



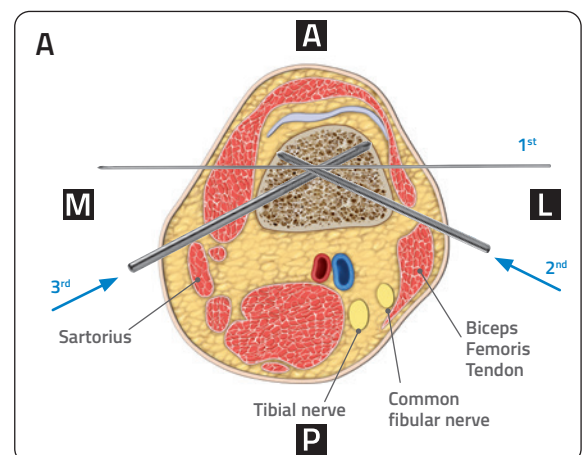
PRECAUTION: Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the anatomical structures.

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.

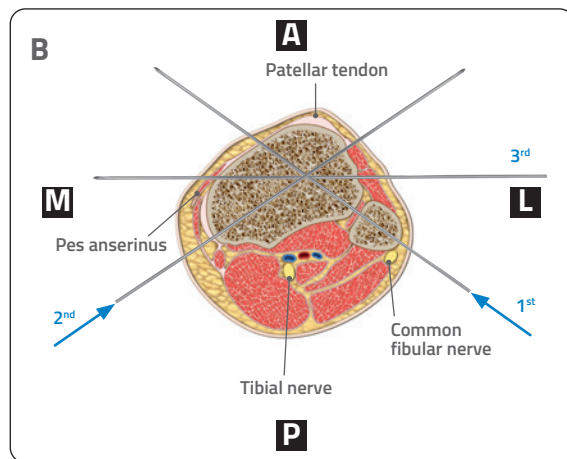


Firstly insert a wire from lateral to medial. Then insert two screws: one screw from postero-lateral to anteromedial, anterior to the Biceps Femoris Tendon, and one screw from postero-medial to anterolateral, anterior to the Sartorius. Wire and screws should be inserted with the knee flexed.



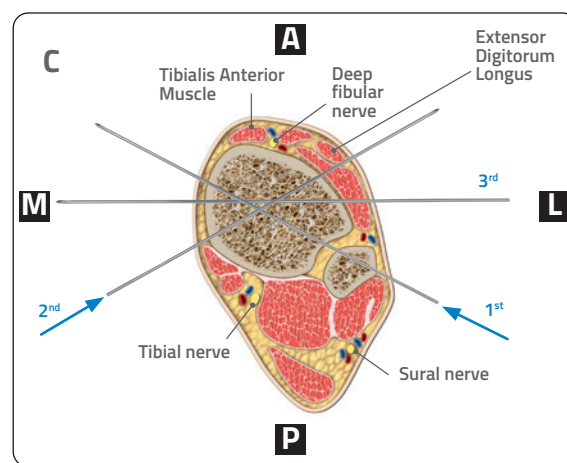
Proximal tibia

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.

SURGICAL PROCEDURE FOR TIBIAL PLATEAU FRACTURE

Part #	Description
886663	TrueLok EVO Ring and Strut Templates

Use the provided templates to choose the appropriate ring sizes according to limb dimension.

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 9**) 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.

For optimal stability three proximal tibial wires 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**).

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. 2**).



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 damage and subsequent loss of fixation.

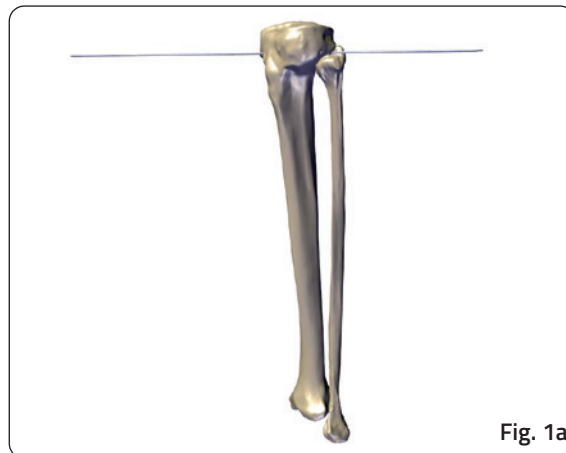


Fig. 1a

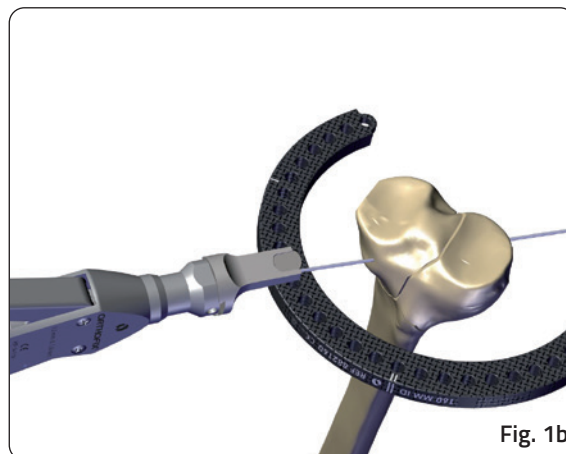


Fig. 1b

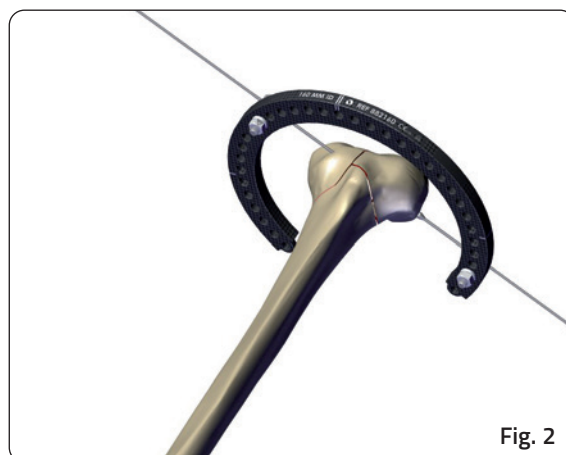


Fig. 2

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

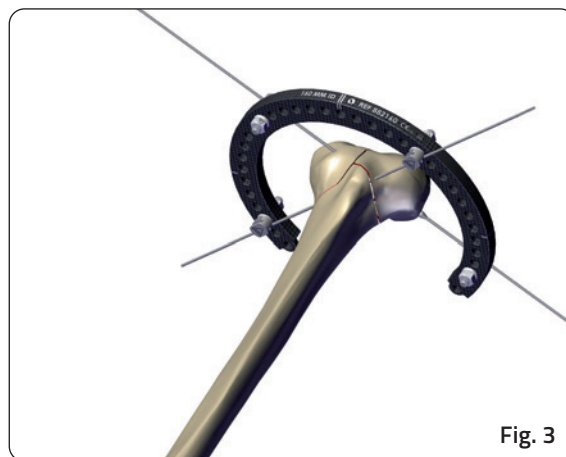


Fig. 3

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



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.

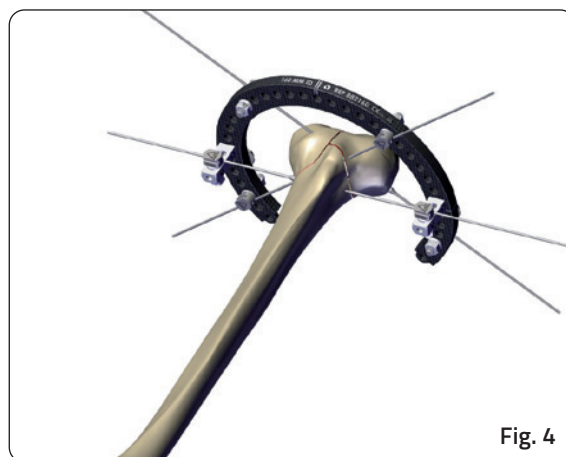


Fig. 4

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. 5**). 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.

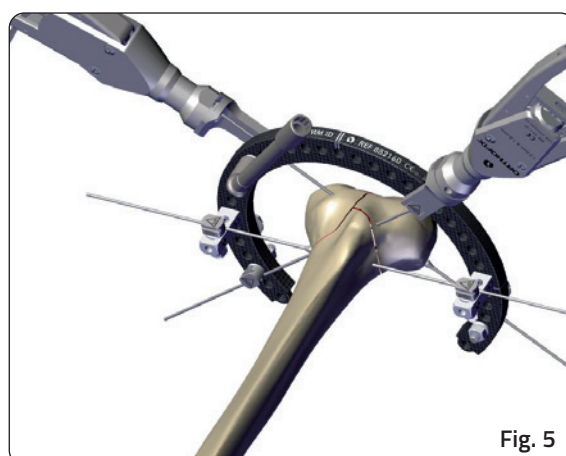


Fig. 5

CLAMP CLOSURE PROCEDURES

This is the knurled knob

This is the half of the clamp that accommodates 6mm bone screws and/or 6-9-12mm rods

This is the half of the clamp that accommodates 4mm bone screws and 9-12mm rods



This is the "OPEN" marking on the metal ring (12 o'clock) with double side arrows (for easier wrench tightening)



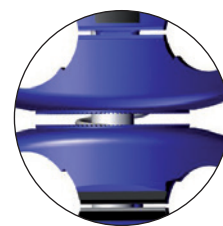
1 FRAME ASSEMBLY



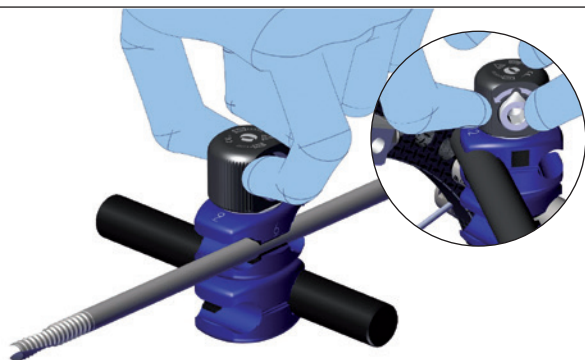
Start position - Clamp open



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

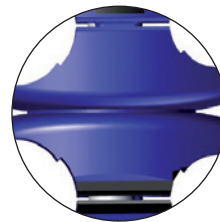


Pre-closure by hand

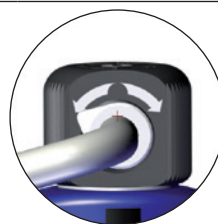
Maintaining the drop in the open position, the knurled knob is turned clockwise.



The two halves of the clamp are now tightened closed, rods and bone screw cannot be inserted anymore.



3 DEFINITIVE FRAME LOCKING



The 5mm Allen Wrench is inserted in the bolt and is turned either clockwise (3 o'clock) or counterclockwise (9 o'clock). Arrows identify the direction for moving the drop in order to engage the cam for final tightening.

GALAXY FIXATION GEMINI™ APPLICATION

Part #	Description
11103	Screw Guide, L100mm
11105	Drill Guide, D4.8mm L80mm
1100201	Drill Bit, D4.8mm length 240mm
91150	Universal T-Wrench
30017	Allen Wrench 5mm
54-1154	TL Wrench Combo 10mm

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 galaxy fixation gemini double universal multipin 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. 6**).



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. 7**))
- 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. 8**)

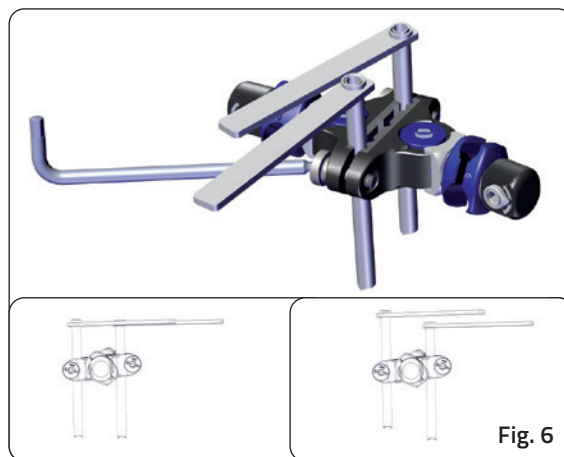


Fig. 6



Fig. 7

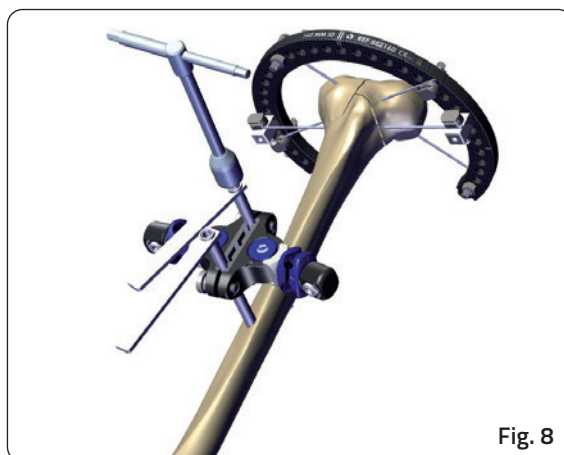


Fig. 8

Once all screws are inserted, remove the screw guides and close the clamp. Where two screws are inserted, use the outer holes of the clamp. Generally in adults three screws are recommended. It is important that the clamp is locked firmly over the screws.



WARNING: The fixator should be applied at a sufficient distance from the skin to allow for postoperative swelling and for cleaning, remembering that the stability of the system depends upon the bone to fixator distance.



WARNING: 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.

Attach two Galaxy TL-HEX Connecting Posts to the ring (**Fig. 9**).

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 opposite each other with respect to the ring center, as far as possible one from one another. The positions of the posts may vary depending on 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 Galaxy Fixation Gemini Universal Single Clamps to the Galaxy TL-HEX Connecting Posts (**Fig. 10**).

Connect them to the central Galaxy Fixation Gemini Double Universal Multipin Clamp through rods of suitable length. Then manually lock all clamps by turning the knurled knob clockwise. Lock all clamps firmly by tightening the cams with the 5mm Allen Wrench (**Fig. 11**).

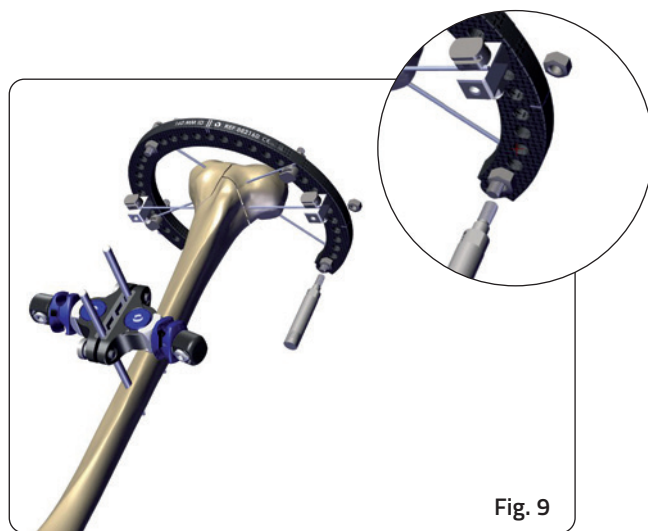


Fig. 9

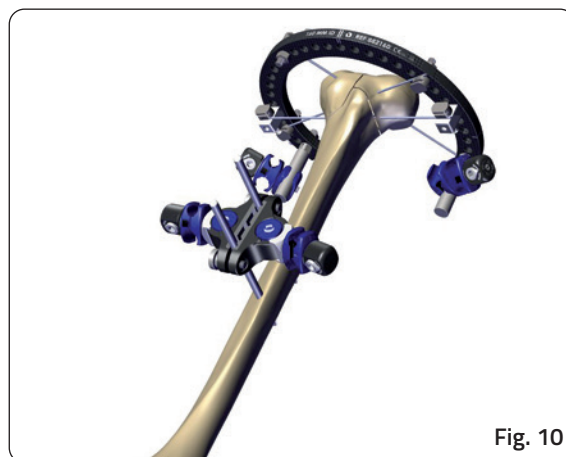


Fig. 10

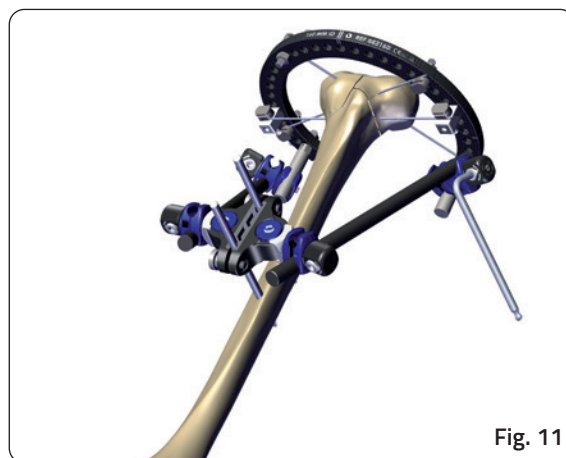


Fig. 11

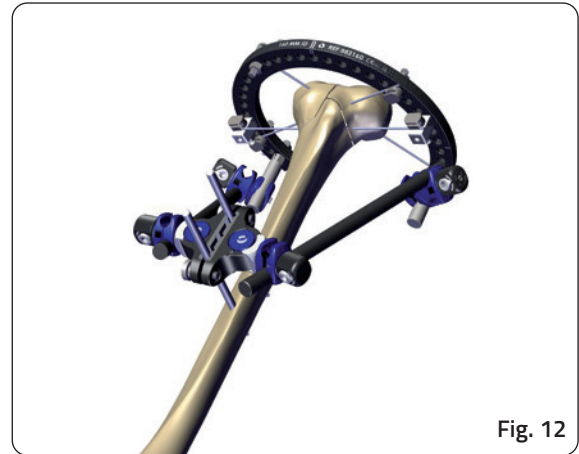


Fig. 12

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 Galaxy Fixation Gemini Universal Single Clamp (**Fig. 13**).

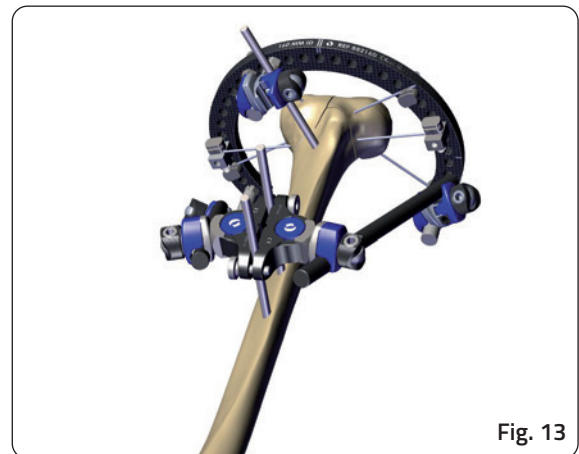


Fig. 13

OPTIONAL ADDITIONAL STEP

The use of a third post is optional when using the Galaxy Fixation Gemini Double Universal Multipin Clamp and 12mm Rods, whereas it is mandatory in combination with the 9mm Rods. Place the third post in a central position between the other two. Connect the third post with a Galaxy Fixation Gemini Universal Single Clamp and use it as a template to insert the bone screw in the most appropriate direction. Then tighten the Galaxy Fixation Gemini Universal Single Clamp as described above.

POST OPERATIVE MANAGEMENT

Depending on the fracture type, reduction, and 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.


FRAME REMOVAL

Part #	Description
91150	Universal T-Wrench
54-1154	TL Wrench Combo 10mm
54-2226	TL 90 degree Tubular Wrench
30017	Allen Wrench 5mm

Untighten all the wire fixation bolts using the appropriate wrenches (54-1154 or 54-2226). Remove the wires with the power drill. Untighten the clamp by turning the drop back to the open position (12 o'clock) using the 30017 Allen Wrench or the Universal T-Wrench with 5mm end (91150). Then turn the knurled knob counterclockwise by hand. Disassemble the frame by removing clamps and rods and remove the entire frame from the limb. Remove all bone screws manually with the Universal T-Wrench (91150) or with a power drill.

MRI SAFETY INFORMATION

In case you are building a MRI conditional frame, the frame shall be accompanied by a MRI Patient Card. 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. The TL-EVO GALAXY FIXATION Hybrid System has been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment.

 Outside the MRI bore MRI Safety Information A person with the TL-EVO GALAXY FIXATION Hybrid System may be safely scanned under the following conditions. Failure to follow these conditions may result in serious injury. CAUTION: All TL-EVO GALAXY FIXATION Hybrid System components must be outside the bore to avoid risk of excessive RF heating.	
Device Name	TL-EVO GALAXY FIXATION Hybrid System
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	15T/m or 1500gauss/cm
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Volume RF body coil
Operating Mode	First level Operating Mode
Maximum Whole-Body SAR	4W/kg (first level control mode)
Maximum Head SAR	3.2W/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 GALAXY FIXATION Hybrid System Components must not extend into the MRI. Therefore, MR scanning of body parts where the TL-EVO GALAXY FIXATION Hybrid System is located is contraindicated.

Non-clinical testing has demonstrated that the TL-EVO GALAXY FIXATION Hybrid System Components are MR Conditional according to the terminology specified in ASTM F2503 "Standard Practice for Marking Medical Devices and Other Items in the Magnetic Resonance Environment".

TL-EVO GALAXY FIXATION Hybrid Systems can only be guaranteed for MRI when using the following TL-EVO Components to build a frame:

TL-EVO COMPONENTS	
Part #	Description
99-882140	TrueLok Evo Rx 5/8 Modular Ring D140mm Sterile
99-882160	TrueLok Evo Rx 5/8 Modular Ring D160mm Sterile
99-882180	TrueLok Evo Rx 5/8 Modular Ring D180mm Sterile
99-882200	TrueLok Evo Rx 5/8 Modular Ring D200mm Sterile
99-885000	TrueLok Evo Nut with Washer Sterile
99-885001	TrueLok Evo Wire Fixation Bolt Sterile
99-885002	TrueLok Evo 8mm Half Pin Fixation Bolt Sterile
99-885003	TrueLok Evo Bolt L16.5mm Sterile
99-885004	TrueLok Evo 2 Holes Post Sterile
99-885005	TrueLok Evo 3 Holes Post Sterile
99-885006	TrueLok Evo 4 Holes Post Sterile
99-885007	TrueLok Evo Half Pin Fixation Bolt Sterile
54-1215	Bayonet Wire With Stopper
54-1216	Bayonet Wire
93031	Galaxy TL-Hex Connecting Post L50

RODS*		
Part #	Description	Qty
12mm RODS		
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
9mm RODS		
939100	Rod 100mm long	2
939150	Rod 150mm long	2
939200	Rod 200mm long	2
939250	Rod 250mm long	2
939300	Rod 300mm long	2

GEMINI CLAMPS*	
Part #	Description
94100	Galaxy Fixation Gemini Universal Single Clamp
94200	Galaxy Fixation Gemini Double Universal Multipin Clamp
94300	Galaxy Fixation Gemini Universal Multipin Clamp

XCALIBER BONE SCREWS*				
Part #	Shaft Ø	Total L	Thread Ø	Thread L
912630	6	6 - 5,6	260	30
912640	6	6 - 5,6	260	40
912650	6	6 - 5,6	260	50
912660	6	6 - 5,6	260	60
912670	6	6 - 5,6	260	70
912680	6	6 - 5,6	260	80
912690	6	6 - 5,6	260	90
911530	6	6 - 5,6	150	30
911540	6	6 - 5,6	150	40
911550	6	6 - 5,6	150	50
911560	6	6 - 5,6	150	60
911570	6	6 - 5,6	150	70
911580	6	6 - 5,6	150	80
911590	6	6 - 5,6	150	90

BONE SCREWS*				
Part #	Shaft Ø	Total L	Thread Ø	Thread L
10190	6	4,5 - 3,5	70	20
10191	6	4,5 - 3,5	80	20
10108	6	4,5 - 3,5	80	30
10135	6	4,5 - 3,5	100	20
10136	6	4,5 - 3,5	100	30
10105	6	4,5 - 3,5	100	40
10137	6	4,5 - 3,5	120	20
10138	6	4,5 - 3,5	120	30
10106	6	4,5 - 3,5	120	40
35100	4	3,3 - 3	70	20
35101	4	3,3 - 3	80	35

* 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.

XCALIBER CYLINDRICAL BONE SCREWS*				
Part #	Shaft Ø	Total L	Thread Ø	Thread L
941625	6	6	180	25
941630	6	6	180	30
941635	6	6	180	35
941640	6	6	180	40
941645	6	6	180	45
941650	6	6	180	50
941660	6	6	180	60
941670	6	6	180	70
941680	6	6	180	80
941690	6	6	180	90
942625	6	6	260	25
942630	6	6	260	30
942635	6	6	260	35
942640	6	6	260	40
942645	6	6	260	45
942650	6	6	260	50
942660	6	6	260	60
942670	6	6	260	70
942680	6	6	260	80
942690	6	6	260	90
941525	6	5	180	25
941530	6	5	180	30
941535	6	5	180	35
941540	6	5	180	40
941545	6	5	180	45
941550	6	5	180	50
941560	6	5	180	60
941570	6	5	180	70
942525	6	5	260	25
942530	6	5	260	30
942535	6	5	260	35
942540	6	5	260	40
942545	6	5	260	45
942550	6	5	260	50
942560	6	5	260	60
942570	6	5	260	70
942580	6	5	260	80
942590	6	5	260	90

XCALIBER CYLINDRICAL BONE SCREWS*				
Part #	Shaft Ø	Total L	Thread Ø	Thread L
944540	6	5	150	40
943420	6	4	100	20
943430	6	4	100	30
943440	6	4	100	40
944420	6	4	120	20
944430	6	4	120	30
944440	6	4	120	40
945420	6	4	150	20
945425	6	4	150	25
945430	6	4	150	30
945435	6	4	150	35
945440	6	4	150	40
946420	6	4	180	20
946430	6	4	180	30
946440	6	4	180	40
947320	4	3	100	20
947325	4	3	100	25
948315	4	3	120	15
948320	4	3	120	20
948325	4	3	120	25
948330	4	3	120	30
948335	4	3	120	35

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

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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