OPERATIVE TECHNIQUE

Galaxy Fixation

Gemini™ System

ORTHOFIX®
ORTHOPEDICS

Galaxy Fixation

Gemini™ System

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

Please kindly refer to the product IFU PQGAL, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

DESCRIPTION

The Galaxy Fixation Gemini™ is a modular external fixator consisting of a series of components that build the external frame. The external frame is connected to the bone by of bone screws. The Galaxy Fixation Gemini can be used as a hybrid system in conjunction with Orthofix Circular External Fixators and Kirschner Wires. Application and removal of the Galaxy Fixation Gemini can be performed with Orthofix general orthopedic instrumentation.

FEATURES AND BENEFITS

Rods

Radiolucent rods are made of carbon fiber and come in three different diameters (12mm, 9mm and 6mm) and various lengths.

Rods **Diameter 12mm** MR

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

** Special order only*

Rods **Diameter 9mm** MR

Part #	Description
939100	Rod 100mm long
939150	Rod 150mm long
939200	Rod 200mm long
939250	Rod 250mm long
939300	Rod 300mm long

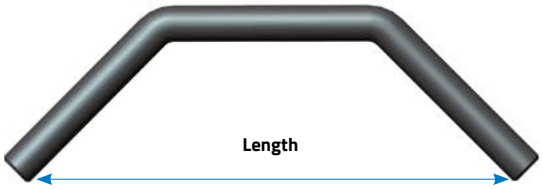
Rods **Diameter 6mm** MR

Part #	Description
936060	Rod 60mm long
936080	Rod 80mm long
936100	Rod 100mm long
936120	Rod 120mm long
936140	Rod 140mm long
936160	Rod 160mm long
936180	Rod 180mm long
936200	Rod 200mm long

L Rod (Aluminum) **Diameter 6mm**

Part #	Description
936010	6mm L Rod

Semi-Circular Rods (Aluminum) **Diam. 12mm**



Part #	Description
932010	Semi-Circular Rod small 180mm long
932020	Semi-Circular Rod medium 215mm long
932030	Semi-Circular Rod large 250mm long

Semi-Circular Rods (Aluminum) **Diam. 9mm**

Part #	Description
939010	Semi-Circular Rod small 115mm long
939020	Semi-Circular Rod medium 140mm long
939030	Semi-Circular Rod large 165mm long

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

Bone Screw

XCALIBER CYLINDRICAL BONE SCREWS

SHAFT DIAMETER 6mm, THREAD DIAMETER 6mm

	Thread length (mm)									
Total length (mm)	**25**	**30**	**35**	**40**	**45**	**50**	**60**	**70**	**80**	**90**
180 QC	99-941625	**99-941630**	99-941635	**99-941640**	99-941645	**99-941650**	99-941660	**99-941670**	*	*
260 QC	99-942625	**99-942630**	99-942635	**99-942640**	99-942645	**99-942650**	99-942660	**99-942670**	*	*

SHAFT DIAMETER 6mm, THREAD DIAMETER 5mm

	Thread length (mm)									
Total length (mm)	**25**	**30**	**35**	**40**	**45**	**50**	**60**	**70**	**80**	**90**
150 QC	-	-	-	99-944540	-	-	-	-	-	-
180 QC	99-941525	**99-941530**	99-941535	**99-941540**	99-941545	**99-941550**	99-941560	**99-941570**	-	-
260 QC	99-942525	**99-942530**	99-942535	**99-942540**	99-942545	**99-942550**	99-942560	**99-942570**	*	*

SHAFT DIAMETER 6mm, THREAD DIAMETER 4mm

	Thread length (mm)				
Total length (mm)	**25**	**25**	**30**	**35**	**40**
100 QC	99-943420	-	99-943430	-	99-943440
120 QC	99-944420	-	99-944430	-	99-944440
150 QC	99-945420	**99-945425**	99-945430	**99-945435**	99-945440
180 QC	99-946420	-	99-946430	-	99-946440

SHAFT DIAMETER 4mm, THREAD DIAMETER 3mm

	Thread length (mm)				
Total length (mm)	**15**	**20**	**25**	**30**	**35**
100 QC	-	**99-947320**	99-947325	-	-
120 QC	99-948315	**99-948320**	99-948325	**99-948330**	99-948335

** Upon request*

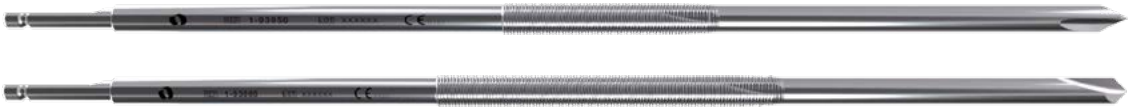
XCALIBER CONICAL BONE SCREWS

Shaft Ø 6mm - Thread 6-5.6mm

	Thread length (mm)						
Total length (mm)	**30**	**40**	**50**	**60**	**70**	**80**	**90**
150	99-911530	**99-911540**	99-911550	**99-911560**	99-911570	**99-911580**	99-911590
260	99-912630	**99-912640**	99-912650	**99-912660**	99-912770	**99-912780**	99-912790

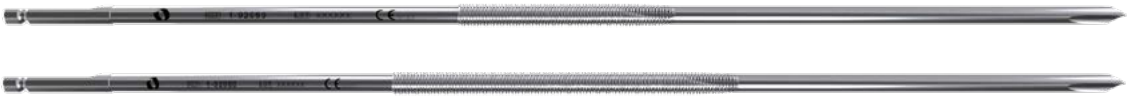
TRANSFIXING PINS

Shaft Ø 6mm - Thread Ø 7mm



Part #	Description
99-1-93050	TRANSFIX PIN 50mm QC STERILE
99-1-93080	TRANSFIX PIN 80mm QC STERILE

Shaft Ø 4mm - Thread Ø 5mm



Part #	Description
99-1-92050	SS TRANSFIXING PIN L 260mm D 4mm THREAD D 5 X L 50mm QC STERILE
99-1-92080	SS TRANSFIXING PIN L 260mm D 4mm THREAD D 5 X L 80mm QC STERILE

All bone screws are also available packaged non sterile. They can be ordered using the above code numbers without 99- [e.g. 941625] Galaxy Fixation Gemini is compatible with all Orthofix Bone Screws with shaft and thread diameters as indicated above. Please refer to Orthofix Product Catalogue. Bone Screws are strictly single patient use.

CLAMPS

WARNING: Components may not be interchangeable between all Orthofix Fixation Systems. Consult individual operative technique guide for interchangeable components.

The Galaxy Fixation Gemini System combines two different clamp designs, colour coded, according to product sales configuration:

- Multiple use Universal Clamps that combine the features of two clamps in one, provided non sterile (blue clamps).
- Single use Standard clamps provided sterile single packed or in ready to use sterile sets (grey and grey-bronze clamps).

Multiple use Universal Clamps

Simple: single clamps can perform rod-to-rod coupling and pin-to-rod coupling.

Versatile: Universal clamps can accommodate different diameters of rods and bone screws providing the modular system with mounting versatility for each anatomical district.

Easy to use: snap-in system, provisional tightening by hand, definitive cam closure in one step. On each clamp slot there is a marker to identify proper rod/bone screw diameter. Preassembled multipin clamps.

Stable: internal teeth and locking profiles designed to provide high torsional strength and avoid components sliding.

Galaxy Fixation Gemini is **MRI Conditional** at 1.5 and 3 Tesla*.

** Refer to dedicated IFU for further information.*

Markers on clamp slots

- Easy identification of rod and pin diameter for each clamp slot

Modified knurled knob and definitive closure mechanism

- Intuitive locking with visible check for definitive locking from any side regardless of clamp position

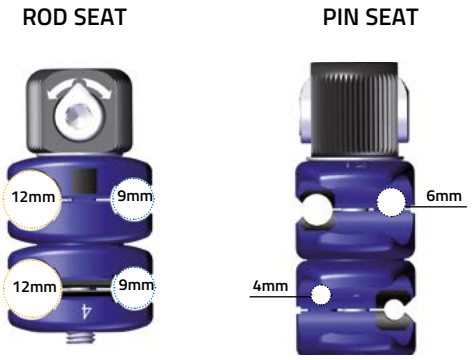
Double closure mechanism hand-tightening pre-closure

- Simplify intra-operative reduction adjustment
- Fast frame assembly
- Ease of use because there is no need for instruments for primary frame stabilization/closure

Notched interface profile of the clamp and wrench definitive tightening

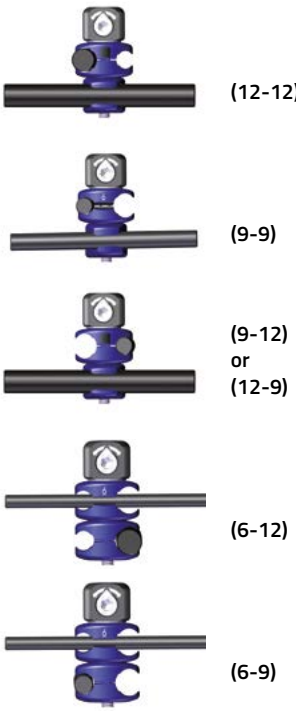
- Provide adequate stability of the frame after final closure

Galaxy Fixation Gemini UNIVERSAL SINGLE CLAMP (94100) MR

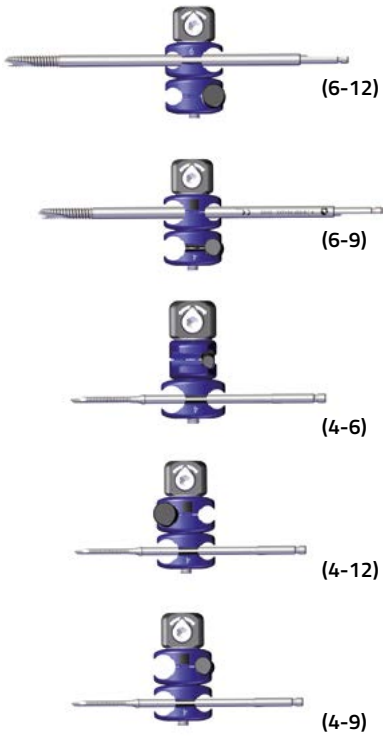


Single clamps can hold 6-9-12mm diameters of rod and 4-6mm diameters of bone screw shaft.

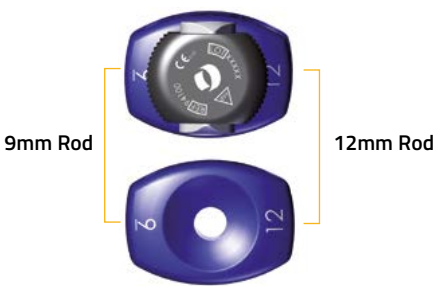
ROD TO ROD COUPLING



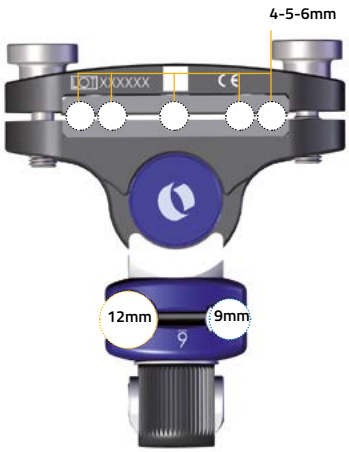
PIN TO ROD COUPLING



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



Galaxy Fixation Gemini UNIVERSAL MULTIPIN CLAMP (94300) MR



Multipin clamps can hold 6-9-12mm diameters of rod and 4-5-6mm diameters of bone screw shaft.

In multiscrew clamps insert minimum two screws in the most external seats, if possible, to increase frame stability.

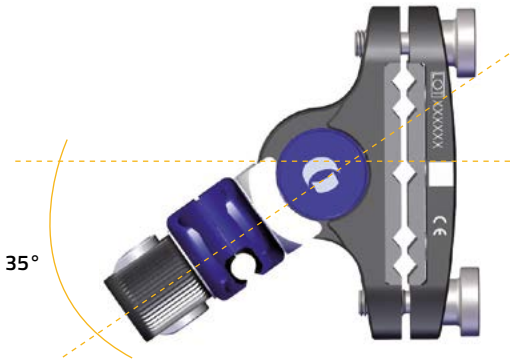
Markers on clamp slots: Easy identification of rod and pin diameter for each clamp slot.

COMPATIBILITY WITH DEFINITIVE ORTHOFIX MONOLATERAL FIXATORS

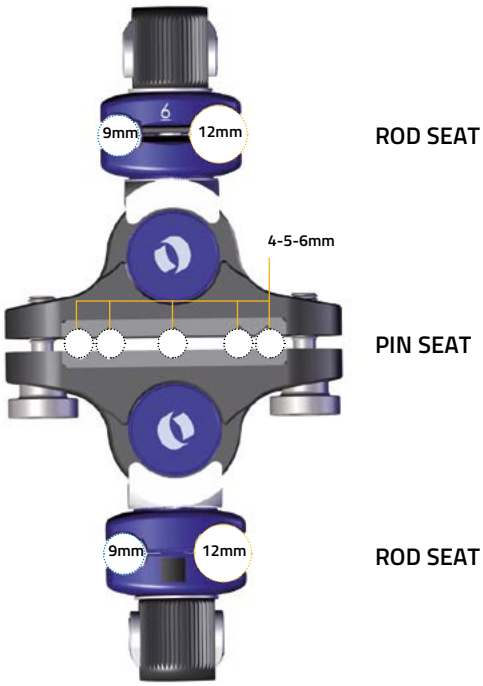
1-3-5 position of the screw-holes refer to the screw position of XCaliber Fixator, main Procallus and LRS ADVanced Clamps.

2-3-4 position of the screw-holes refer to the position of Small Blue DAF and main LRS Paediatric Clamps.

ANGULATION



Galaxy Fixation Gemini DOUBLE UNIVERSAL MULTIPIN CLAMP (94200) MR



Multipin clamps can hold 6-9-12mm diameters of rod and 4-5-6mm diameters of bone screw shaft.

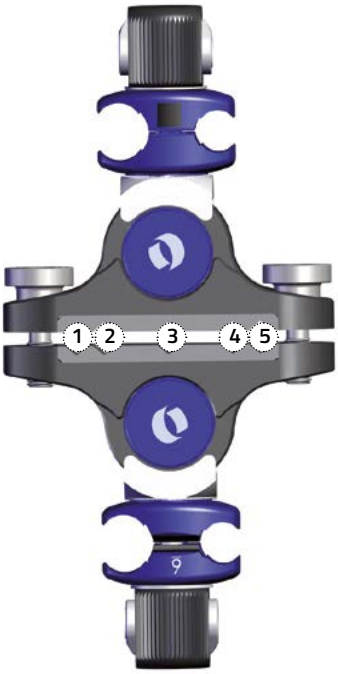
In multiscrew clamps insert minimum two screws in the most external seats, if possible, to increase frame stability.

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

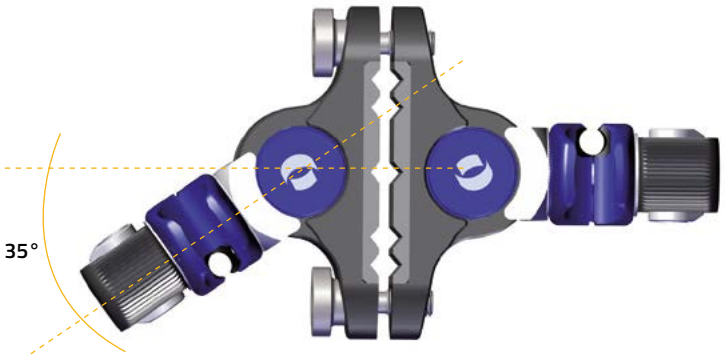
COMPATIBILITY WITH DEFINITIVE ORTHOFIX MONOLATERAL FIXATORS

1-3-5 position of the screw-holes refer to the screw position of XCaliber Fixator, main Procallus and LRS ADVanced Clamps.

2-3-4 position of the screw-holes refer to the position of Small Blue DAF and main LRS Paediatric Clamps.



ANGULATION



Universal clamps are provided in non-sterile configuration only. Please refer to “Equipment required” for detailed information.

Single use Standard Clamps

Simple: single clamps can perform rod-to-rod coupling and pin-to-rod coupling.

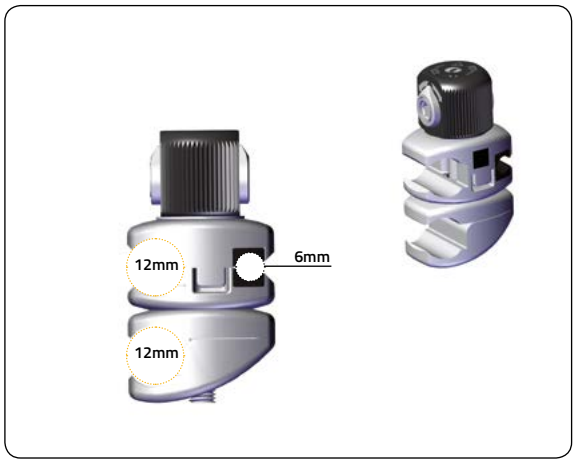
Easy to use: snap-in system, provisional tightening by hand, definitive cam closure in one step.

Stable: internal teeth and locking profiles designed to provide high torsional strength and avoid components sliding.

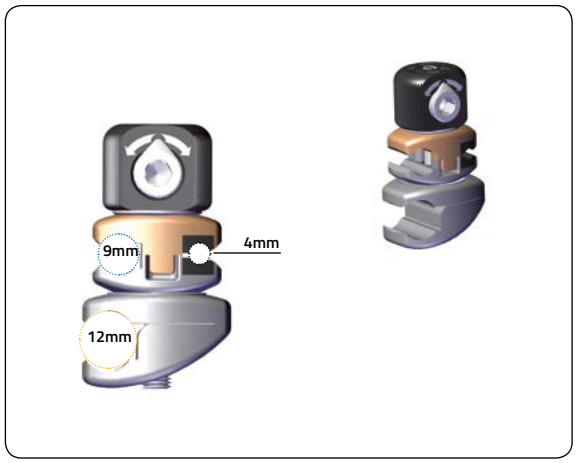
Galaxy Fixation Gemini is **MRI Conditional** at 1.5 and 3 Tesla*.

** Refer to dedicated IFU for further information.*

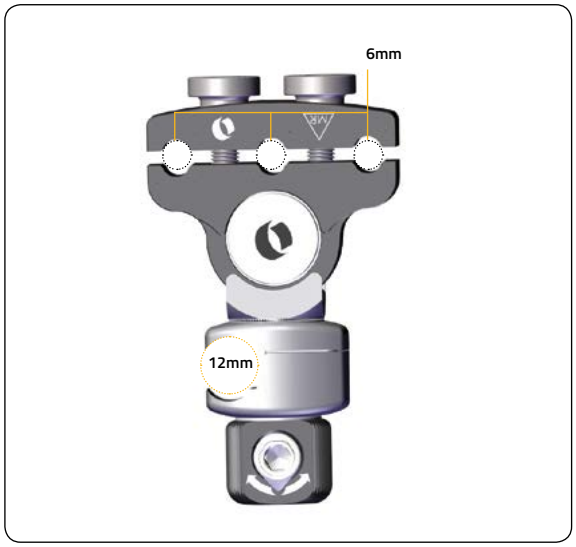
Galaxy Fixation Gemini SINGLE CLAMP 99-94010 MR



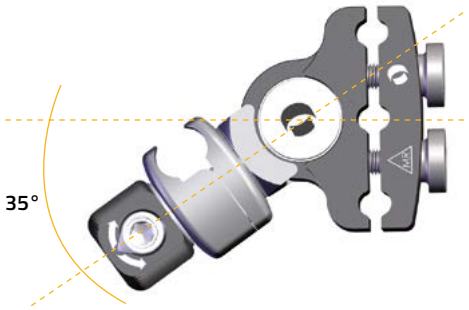
Galaxy Fixation Gemini TRANSITIONAL SINGLE CLAMP 99-94030 MR



Galaxy Fixation Gemini MULTIPIN CLAMP 99-94020 MR



ANGULATION

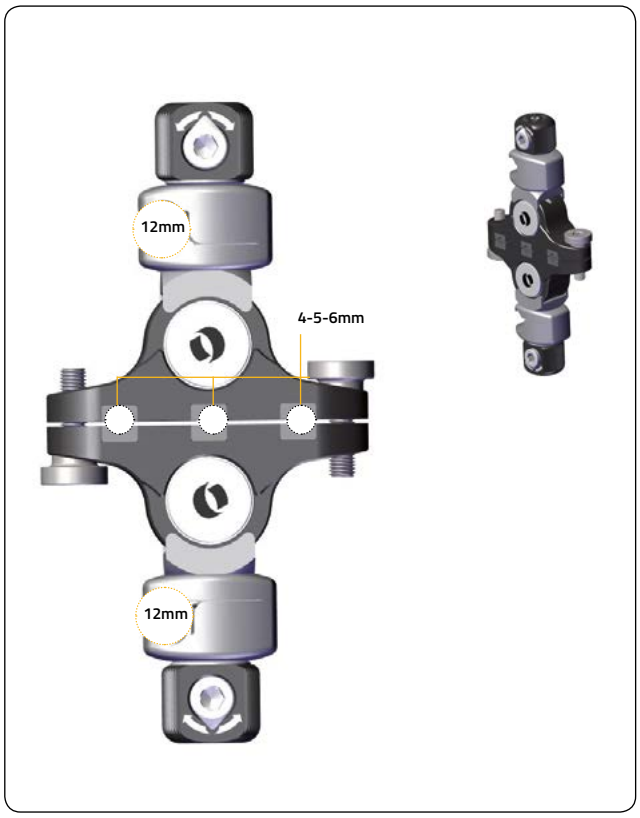


In multiscrew clamps insert minimum two screws in the most external seats, if possible, to increase frame stability.

Position of the screw-holes refers to the screw position of XCaliber Fixator, main Procallus and LRS ADVanced Clamps.

Galaxy Fixation Gemini DOUBLE MULTIPIN CLAMP

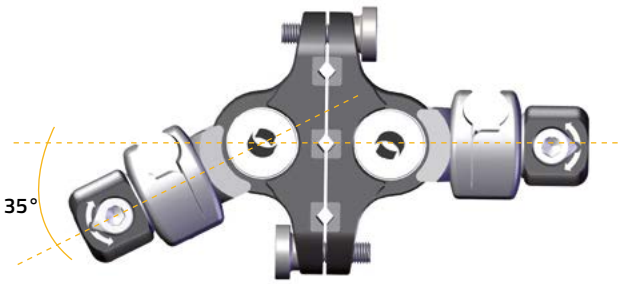
99-94040 MR



In multiscrew clamps insert minimum two screws in the most external seats, if possible, to increase frame stability.

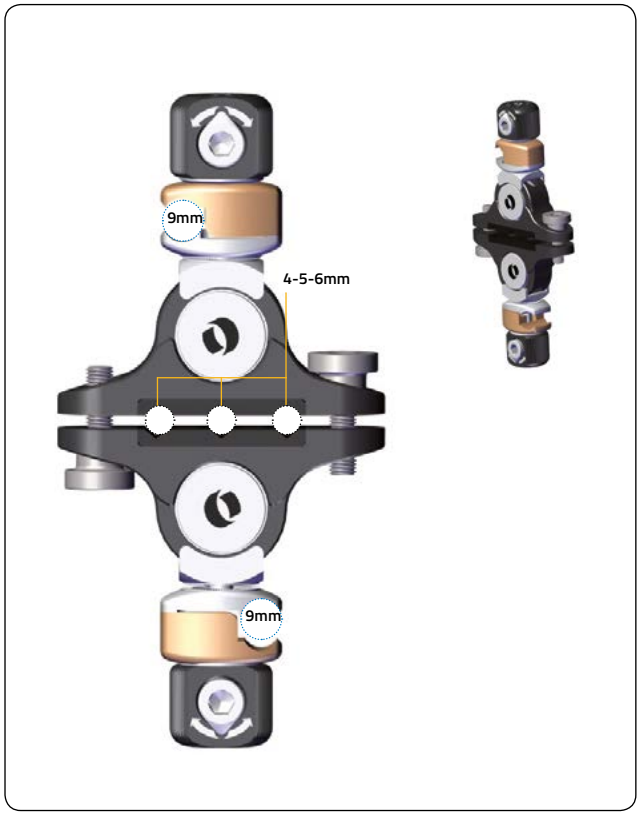
Position of the screw-holes refers to the screw position of XCaliber Fixator, main Procallus and LRS ADVanced Clamps.

ANGULATION



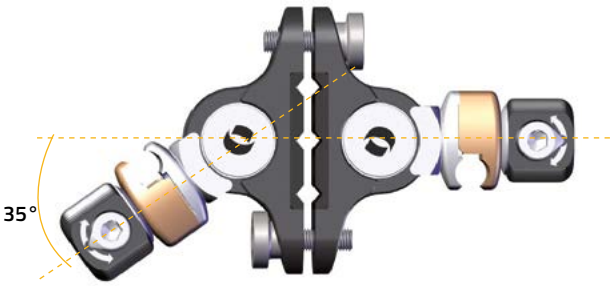
Galaxy Fixation Gemini DOUBLE MULTIPIN CLAMP MEDIUM

99-94140 MR



In multiscrew clamps insert minimum two screws in the most external seats, if possible, to increase frame stability.

ANGULATION



Standard clamps are provided in sterile configuration only.

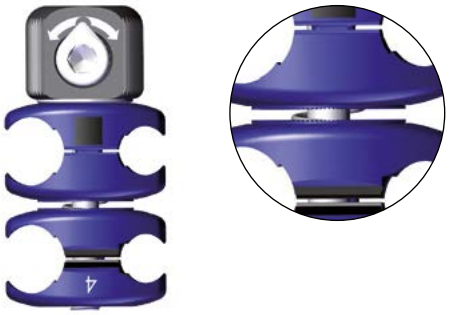
Please refer to “Equipment required” for detailed information.

Clamp Closure Procedure

Suitable also for DCO because no instrumentation is needed to initially stabilize reduction, just hand-tightening. Compared with Galaxy Fixation System, the closure mechanism of universal and standard Galaxy Fixation Gemini Clamps has been modified: bigger black knurled knob (for an easier hand tightening) and double side arrows (for easier wrench tightening).

Starting position

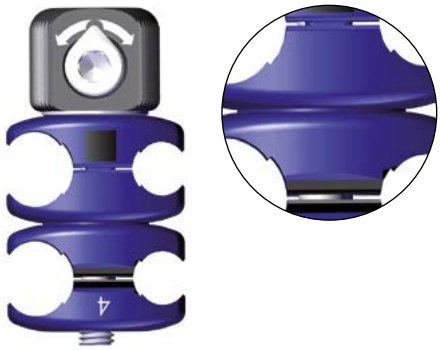
Start position, clamp open



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

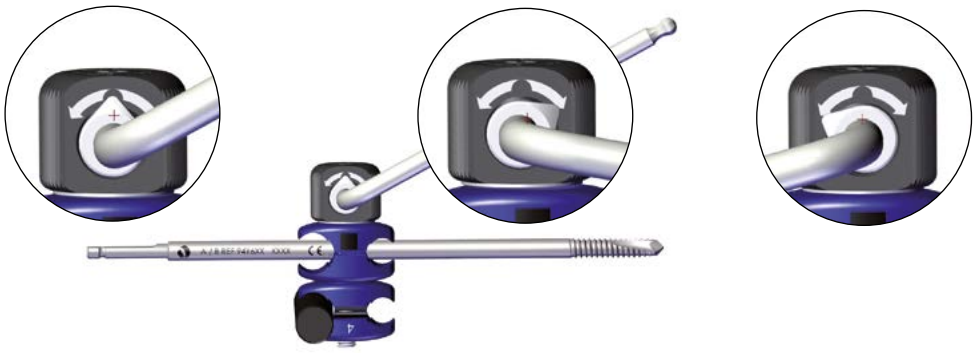
Preliminary closure and fracture reduction

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.

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.

Additional Components for Hybrid Frames

Part #	Description
93031*	GALAXY TL-HEX CONNECTING POST L 50mm D 12mm
93032*	GALAXY TL-HEX CONNECTING POST L 100mm D 12mm

** Connecting Posts are also available single packed and sterile. They can be ordered using the above code numbers preceded by 99- (e.g. 99-93031).*

The Galaxy TL-HEX Connecting Posts permit the assembly of hybrid frames and are compatible with **TL-HEX TrueLok Hexapod System®** and Galaxy Fixation Gemini.

For additional important medical information consult Instructions For Use PQTLK and related operative technique.

The Galaxy TL-HEX Connecting Posts permit the assembly of hybrid frames and are compatible with **TrueLok™ EVO** and Galaxy Fixation Gemini.

For additional important medical information consult Instructions For Use PQEVO and related operative technique.

EQUIPMENT REQUIRED

Single codes are available in NON-Sterile or Sterile single pack according to the table below:

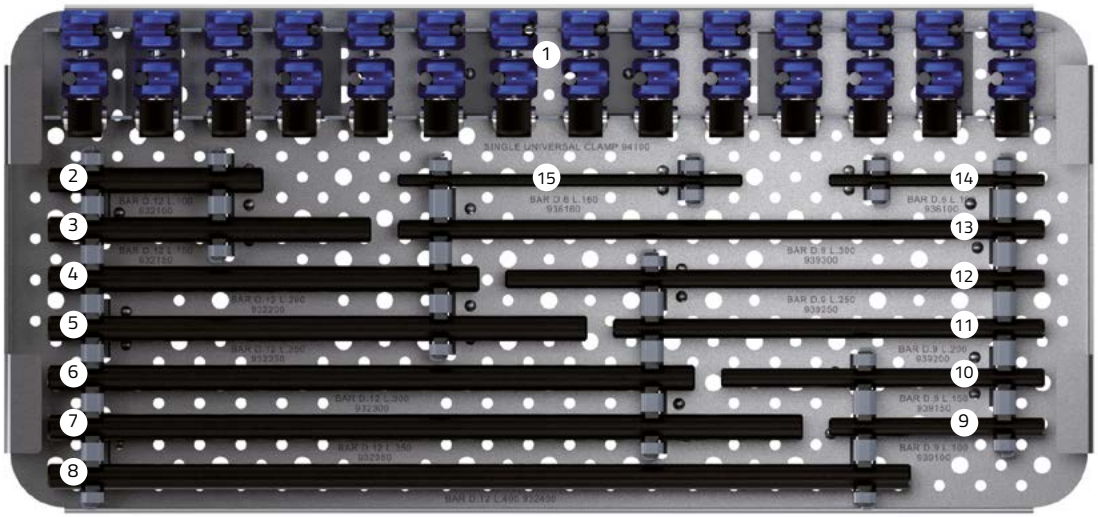
Clamps		
Part #		Description
Non Sterile Configuration	Sterile Configuration	
94100	-	GALAXY FIXATION GEMINI UNIVERSAL SINGLE CLAMP
94200	-	GALAXY FIXATION GEMINI DOUBLE UNIVERSAL MULTIPIN CLAMP
94300	-	GALAXY FIXATION GEMINI UNIVERSAL MULTIPIN CLAMP
-	**99-94010**	GALAXY FIXATION GEMINI SINGLE CLAMP
-	**99-94030**	GALAXY FIXATION GEMINI TRANSITIONAL SINGLE CLAMP
-	**99-94040**	GALAXY FIXATION GEMINI DOUBLE MULTIPIN CLAMP
-	**99-94140**	GALAXY FIXATION GEMINI DOUBLE MULTIPIN CLAMP MEDIUM
-	**99-94020**	GALAXY FIXATION GEMINI MULTIPIN CLAMP

Universal Clamps

Galaxy Fixation Gemini Universal Clamps are available in non-sterile configuration as follow.

Part #	Description
94600	GALAXY FIXATION GEMINI STERILIZATION TRAY EMPTY

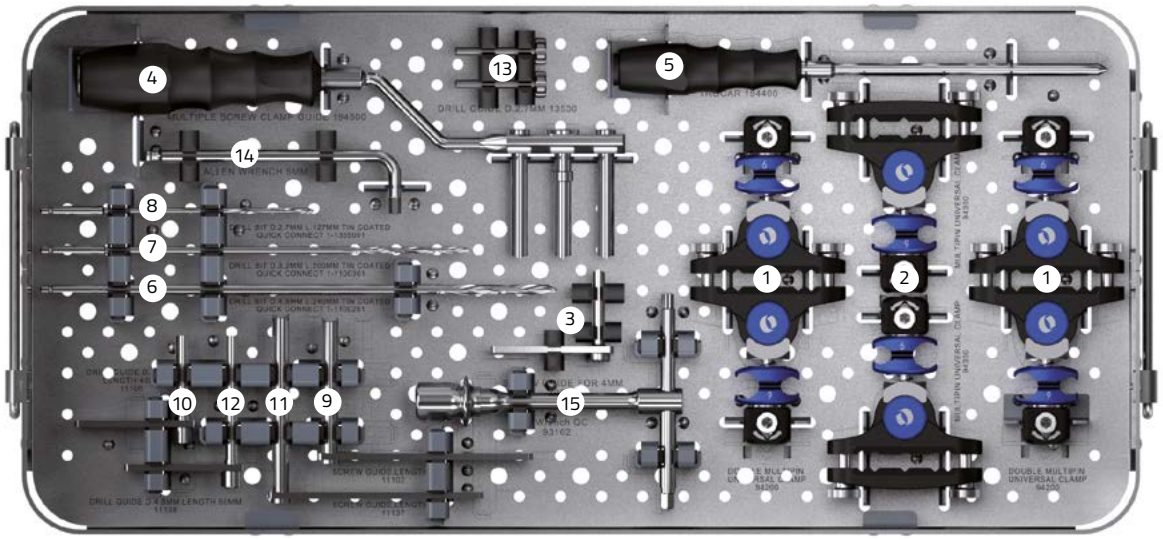
Top Layer



Top Layer			
Part #		Description	Qty
94100	1	GALAXY FIXATION GEMINI UNIVERSAL SINGLE CLAMP	14
932100	2	ROD D 12mm L 100mm	2
932150	3	ROD D 12mm L 150mm	2
932200	4	ROD D 12mm L 200mm	2
932250	5	ROD D 12mm L 250mm	2
932300	6	ROD D 12mm L 300mm	2
932350	7	ROD D 12mm L 350mm	2

Top Layer			
Part #		Description	Qty
932400	8	ROD D 12mm L 400mm	2
939100	9	ROD D 9mm L 100mm	2
939150	10	ROD D 9mm L 150mm	2
939200	11	ROD D 9mm L 200mm	2
939250	12	ROD D 9mm L 250mm	2
939300	13	ROD D 9mm L 300mm	2
936100	14	ROD D 6mm L 100mm	2
936160	15	ROD D 6mm L 160mm	2

Bottom Layer



Bottom Layer

Part #		Description	Qty
94200	1	Galaxy Fixation Gemini DOUBLE UNIVERSAL MULTIPIN CLAMP	2
94300	2	Galaxy Fixation Gemini UNIVERSAL MULTI-PIN CLAMP	2
19995	3	SCREW GUIDE	2
194500	4	Galaxy Fixation Gemini SCREW GUIDE	1
194400	5	Galaxy Fixation Gemini TROCAR	1
1-1100201	6	DRILL BIT D 4.8mm L 240mm TIN COATED - QC	2
1-1100301	7	DRILL BIT D 3.2mm L 200mm TIN COATED - QC	2
1-1355001	8	DRILL BIT D 2.7mm L 127mm TIN COATED - QC	2
11102	9	SCREW GUIDE, L 60mm	2
11106	10	DRILL GUIDE D 3.2mm L 40mm	2
11137	11	SCREW GUIDE, LENGTH 80mm	2
11138	12	DRILL GUIDE D 4.8mm L 60mm	2
13530	13	DRILL GUIDE D 2.7mm	2
30017	14	ALLEN WRENCH 5mm	1
93162	15	T-WRENCH HEXAGON 5-5 QC	2
or			
91150		UNIVERSAL T-WRENCH	2

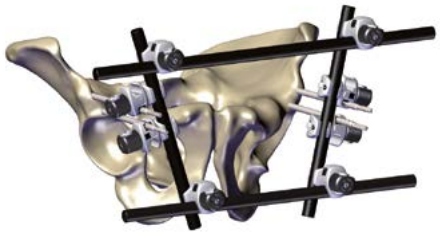
Standard Clamps

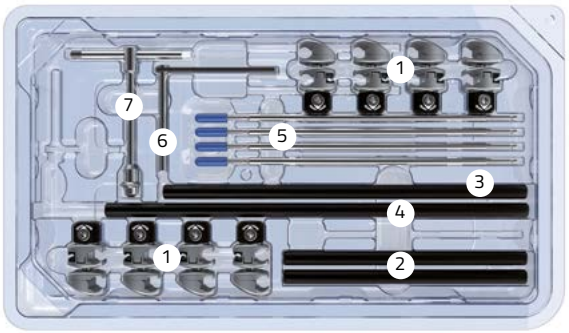
Galaxy Fixation Gemini is ideal for DCO (Damage Control Orthopaedics) because it is available in ready-to-use sterile sets. Sterile sets composition is as follow:

99-94710 GALAXY FIXATION GEMINI PELVIS SET COMPLETE STERILE

Consisting of:

Part #		Description	Qty
94010	1	Galaxy Fixation Gemini SINGLE CLAMP	8
932200	2	ROD D 12mm L 200mm	2
932300	3	ROD D 12mm L 300mm	1
932350	4	ROD D 12mm L 350mm	1
942540	5	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6mm THREAD 5mm L 260/40 QC	4
11137	6	SCREW GUIDE, L 80mm	1
93160	7	T-WRENCH QC	1

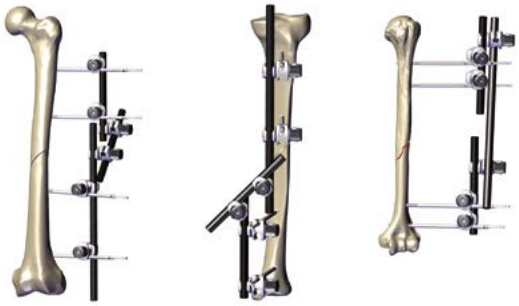


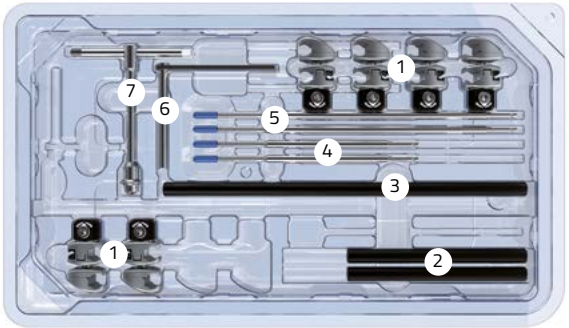


99-94720 GALAXY FIXATION GEMINI Z FRAME SET COMPLETE STERILE

Consisting of:

Part #		Description	Qty
94010	1	Galaxy Fixation Gemini SINGLE CLAMP	6
932150	2	ROD D 12mm L 150mm	2
932300	3	ROD D 12mm L 300mm	1
941550	4	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6mm THREAD 5mm L 180/50 QC	2
942550	5	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6mm THREAD 5mm L 260/50 QC	2
11137	6	SCREW GUIDE, L 80mm	1
93160	7	T-WRENCH QC	1

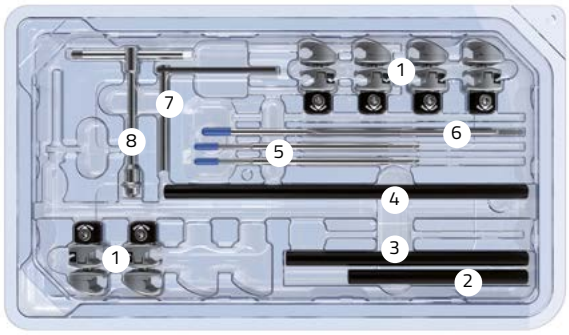




99-94730 GALAXY FIXATION GEMINI ANKLE 6MM SET COMPLETE STERILE

Consisting of:

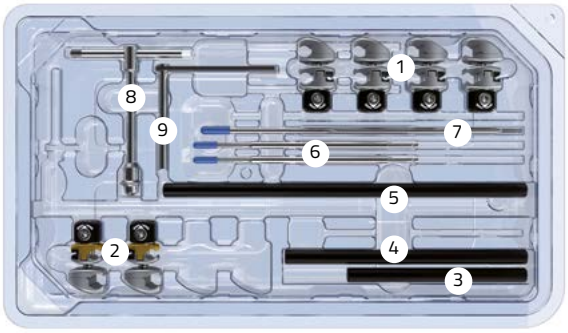
Part #		Description	Qty
94010	1	Galaxy Fixation Gemini SINGLE CLAMP	6
932150	2	ROD D 12mm L 150mm	1
932200	3	ROD D 12mm L 200mm	1
932300	4	ROD D 12mm L 300mm	1
941540	5	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6mm THREAD 5MM L 180/40 QC	2
1-93080	6	TRANSFIX PIN 80mm QC D6mm	1
11102	7	SCREW GUIDE, L 60mm	1
93160	8	T-WRENCH QC	1



99-94740 GALAXY FIXATION GEMINI ANKLE 4MM SET COMPLETE STERILE

Consisting of:

Part #		Description	Qty
94010	1	Galaxy Fixation Gemini SINGLE CLAMP	4
94030	2	Galaxy Fixation Gemini TRANSITIONAL SINGLE CLAMP	2
932150	3	ROD D 12mm L 150mm	1
932200	4	ROD D 12mm L 200mm	1
932300	5	ROD D 12mm L 300mm	1
941540	6	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6mm THREAD 5MM L 180/40 QC	2
1-92080	7	TRANSFIX PIN 80mm QC D4mm	1
93160	8	T-WRENCH QC	1
11102	9	SCREW GUIDE, L 60mm	1



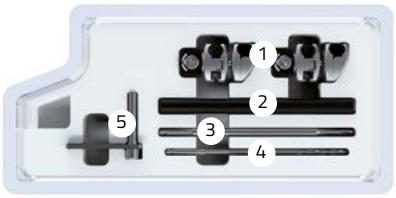
99-94750 GALAXY FIXATION GEMINI METATARSAL SET COMPLETE STERILE*,**

Consisting of:

Part #		Description	Qty
94010	1	Galaxy Fixation Gemini SINGLE CLAMP	2
932150	2	ROD D 12mm L 150mm	1
945425	3	SELFDRILLING XCALIBER CYLINDRICAL SCREW SS L 150/25MM D 6/4MM QC	1
1-1300301	4	DRILL BIT D 3.2mm L 140mm TIN COATED - QC	1
11106	5	DRILL GUIDE D 3.2mm L 40mm	1

** 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.*

*** To be used in combination with ankle kit (99-94730 or 99-94740).*

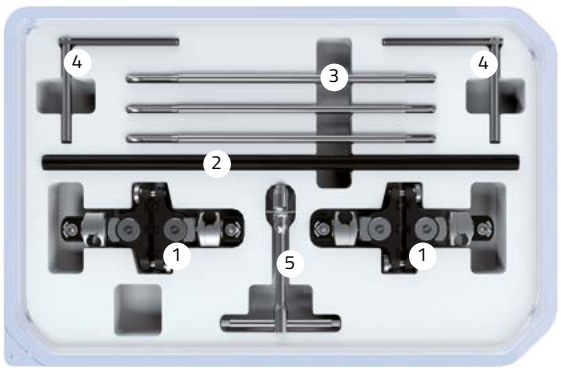


99-94760 GALAXY FIXATION GEMINI QUADRILATERAL SET COMPLETE STERILE*

Consisting of:

Part #		Description	Qty
94040	1	Galaxy Fixation Gemini DOUBLE MULTIPIN CLAMP	2
932400	2	ROD D 12mm L 400mm	2
942540	3	SELF DRILLING XCALIBER CYLINDRICAL SCREW SHAFT D 6mm THREAD 5mm L 260/40 QC	6
11137	4	SCREW GUIDE, LENGTH 80mm	2
93160	5	T-WRENCH QC	1

** 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.*



KEY PRINCIPLES FOR STABILITY IN EXTERNAL FIXATION

N. Giotakis ▪ B. Narayan. Stability with unilateral external fixation in the tibia. Strat Traum Limb Recon (2007) 2:13–20

Three variables that directly influence the stability of the external fixator are:

- The bone–pin interface
- The components of the fixator
- The fixator configuration

THE BONE-PIN INTERFACE

Two important parameters that influence interface stresses and bone hold are pin diameter and interference. Larger diameter pins have a higher resistance to bending forces. This in turn can reduce the stresses at the bone–pin interface. The limit to increasing pin size is set by the diameter of the bone in which the pin is inserted. In practice it is advisable to keep pin sizes to within a third of the diameter of the bone to reduce the risk of fracture on removal of the half-pin. Interference is a measure of the 'grip' the pin has on bone. Maximising interference at the beginning serves to promote bone hold for longer. However this cannot be achieved by simply reducing the size of the pilot drill hole and increasing the major diameter of the pin; such a situation can lead to micro fractures, or crack propagation when the pin is forced into a small pilot hole.

THE COMPONENTS OF THE FIXATOR

Fixator components are:

1. pin and rod clamps
2. connecting bars

It is the responsibility of the surgeon to ensure the clamps are tightened very securely when the fixator has been applied, as loose clamps are not infrequently responsible for loss of fracture control. Connecting bars are available in different lengths. Double stacking the bars improves bending stiffness in the plane of the half pins but does not increase stability in the orthogonal plane or improve resistance to torsion **(Fig. A)**.

The way by which the fixator is assembled can change stability through:

1. the number and spread of pins along the segments, and
2. the distance between connecting rods and bone.

According to the general principles of external fixation, an increase in stiffness is provided by increasing the number of screws from two to three in any one segment. The added benefit from increasing the number of screws from three to four is minimal, therefore three screws per segment is advised. The external fixator configuration will depend on the amount of bone contact at the fracture site, the fracture pattern and the segment or segments of bone involved.

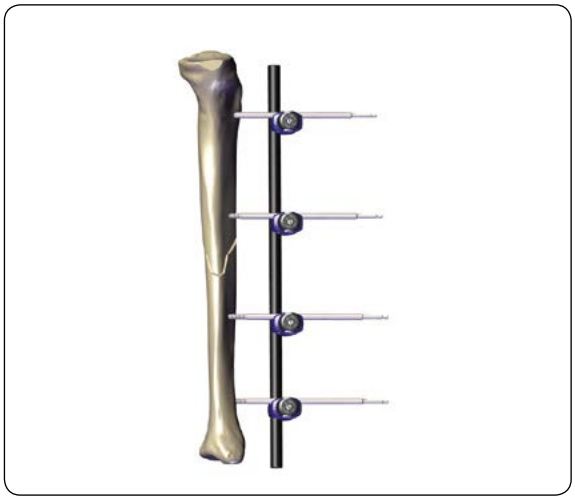


Fig. A

This manual provides examples of how fixator configuration can be augmented in some common fracture patterns to create stability sufficient to allow rehabilitation of the patient. As for screw spread, the "near and far" rule provides a guide: screws should be spread along a segment of bone such that the segment is spanned. The proximity of any screw to the fracture itself is cautioned, as the screw may be within the fracture haematoma and thereby carry the risk of a screw site infection spreading to within the fracture. A rule of thumb of staying at least 2cm from the nearest fracture line helps **(Fig. B)**.

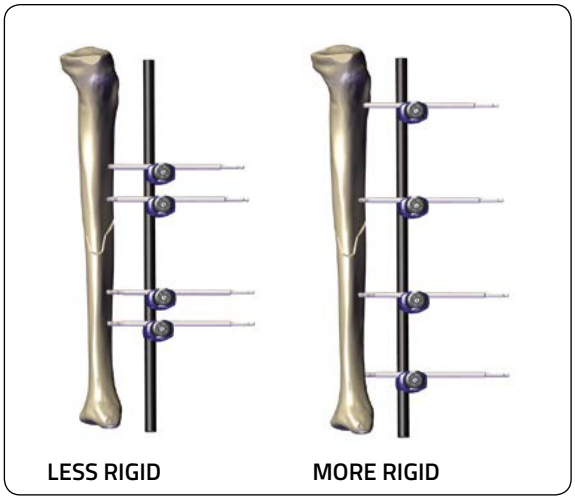


Fig. B

The distance of the connecting bar from bone is determined by the depth of soft tissue in between. Bringing the connecting bar closer to bone improves stability. In general, it should be kept as close as possible with enough room to facilitate screw site care 40-50mm (roughly 2 finger breadths) from the bone surface if feasible **(Fig. C)**.

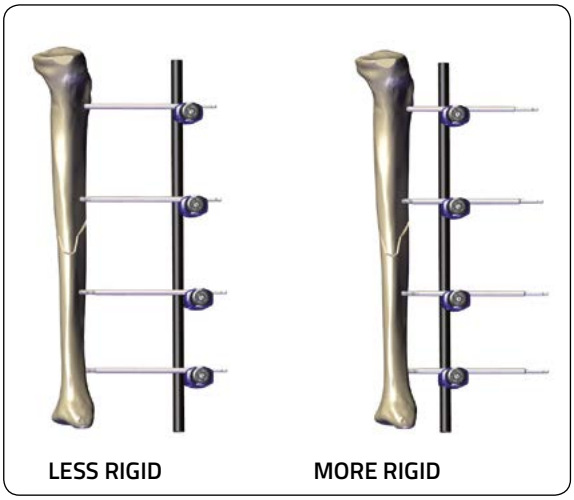


Fig. C

BIPLANAR UNILATERAL CONFIGURATION

Additional stability can be achieved with a biplanar unilateral configuration, which has particular advantages for control of bending in both sagittal and coronal planes (and in planes in between) as well as high resistance against torsion **(Fig. D)**.

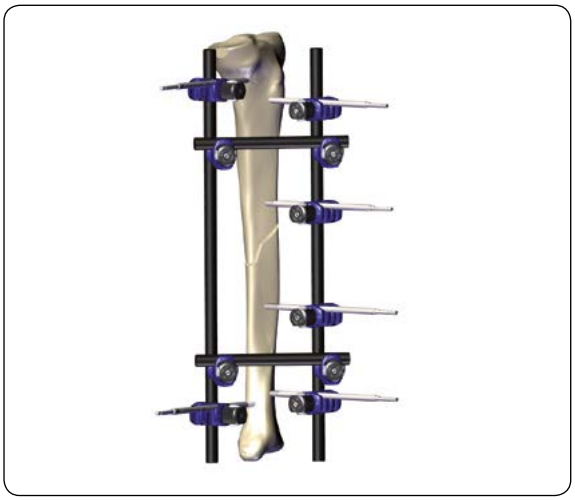
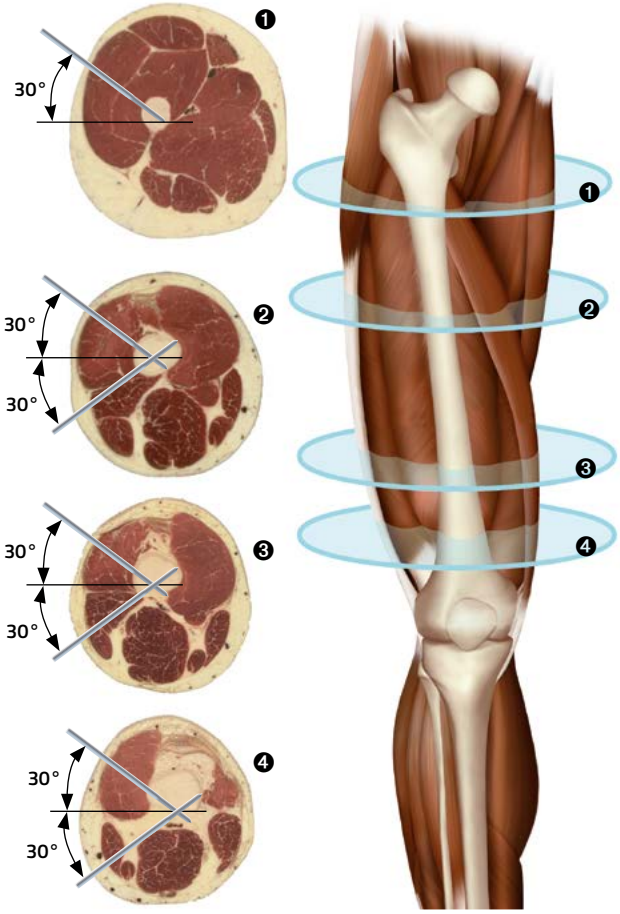


Fig. D

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.



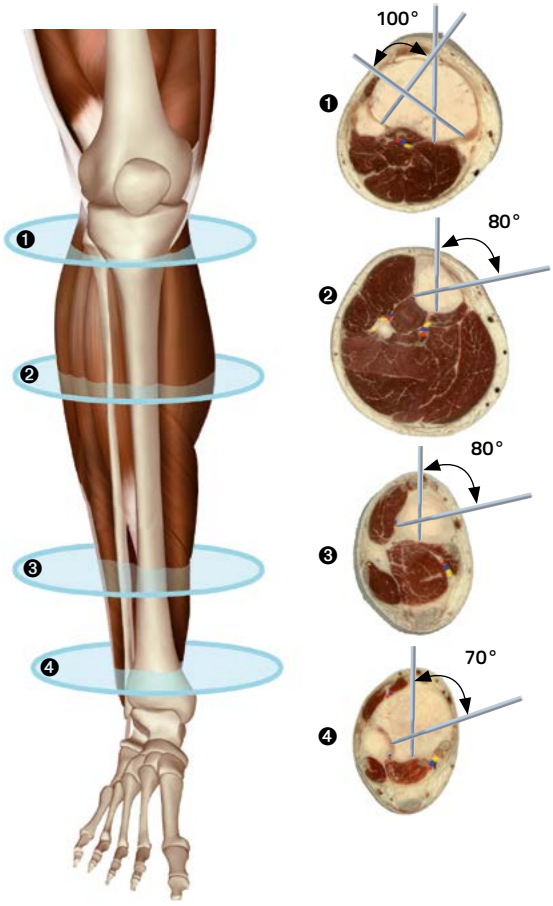
FEMORAL APPLICATION

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.
In damage control scenarios, the anterolateral plane is recommended. This facilitates:

a. Easy connection to tibial assembly in order to span the knee securely.
b. Sufficient clearance to enable lateral submuscular plating of the femur, should this be the desired conversion to definitive stabilization.

TIBIAL APPLICATION

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).



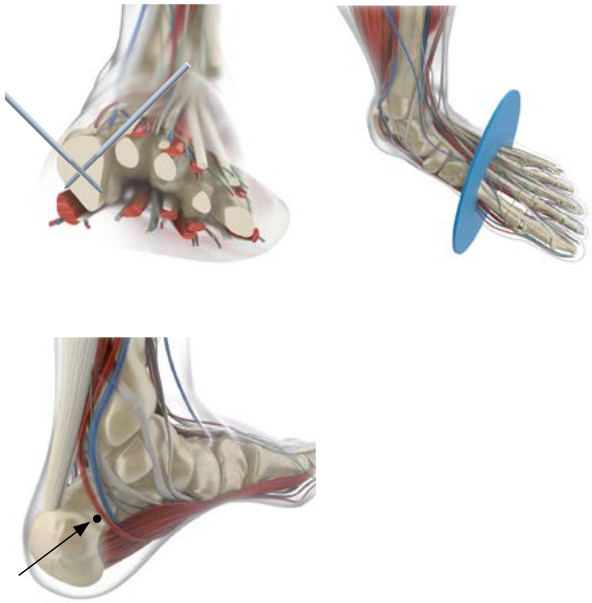
KNEE APPLICATION

(Damage control configuration for distal periarticular fracture of the femur or tibia). The femoral screws are anterolateral whereas the tibial ones are sagittal. The femoral rod is attached laterally and the tibial rod medially to the screws. An oblique cross connection with a third rod is made. Additional screws can be inserted from this cross connecting rod into the distal femur or proximal tibia.

ANKLE APPLICATION
Screw insertion in the metatarsal bone is within the safe corridors illustrated in the cross-sections.

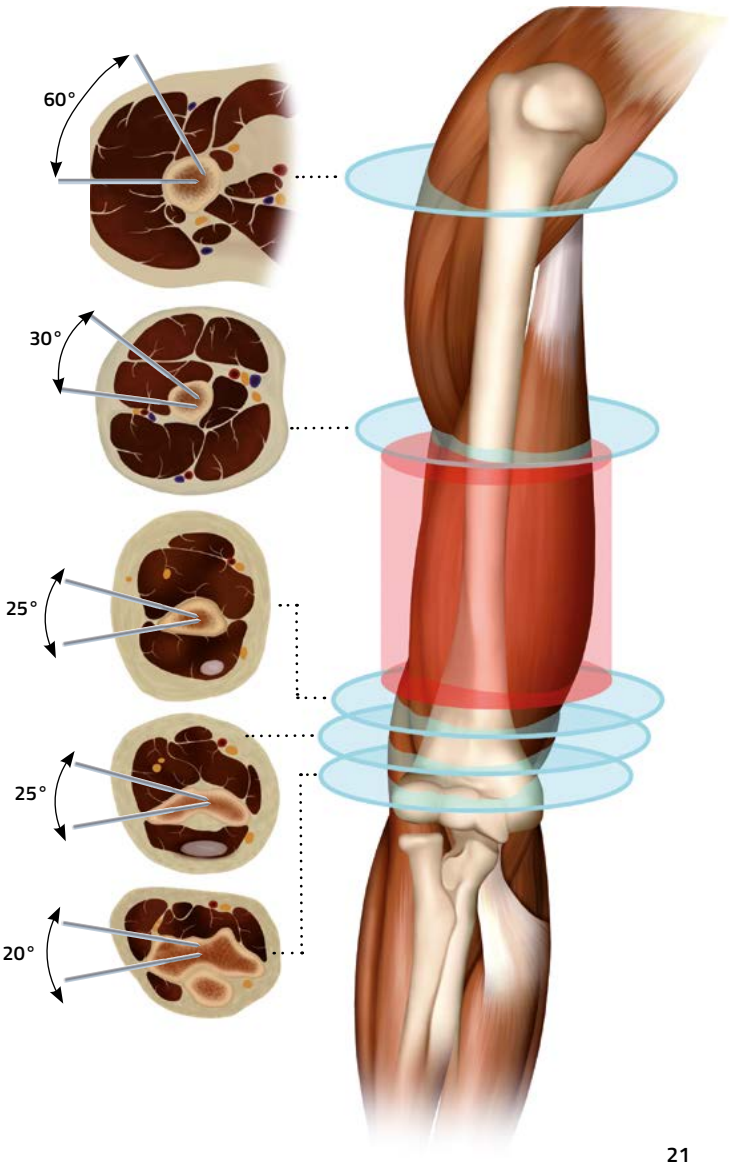
Transfixing pins can be inserted in the medial aspect of the calcaneus, ensuring the entry point is away from the posterior tibial artery and nerve.

This fixation can be supplemented in the case of the first metatarsal base using a threaded half pin. These can be inserted into the centre of the metatarsal base from the dorsal aspect of the foot. If a first metatarsal pin is used, care must be taken to spread the soft tissue to protect the dorsal neurovascular structures.



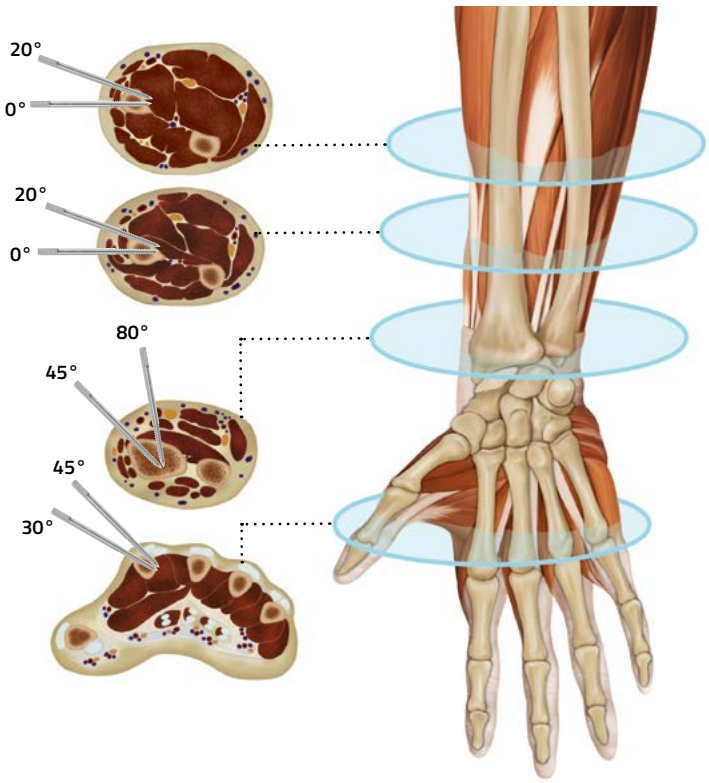
Upper Limb

HUMERUS APPLICATION
When dealing with the humerus, consideration should be given to the radial, axillary, musculocutaneous, ulnar and median nerves, and brachial artery and vein. Proximally, screws should be inserted distal to the level of the axillary nerve. They can be placed from a lateral approach or ventrolateral direction. The middle segment of the humerus (shaded in red) should be avoided as the radial nerve has a variable course in this area. Distally, a screw inserted from the lateral side between the triceps and brachioradialis muscles will avoid the radial nerve as long as it is just proximal to the upper border of the olecranon fossa. A more proximal screw can be inserted just medial to the lateral border of biceps, thereby avoiding the terminal branch of the musculocutaneous nerve. An alternative is a bone screw inserted from the dorsal surface.



WRIST APPLICATION

Proximal screws are placed within the middle third of the radius. At this level the radius is covered by the tendons of extensor carpi radialis longus (ECRL) and extensor carpi radialis brevis (ECRB) as well as the extensor digitorum communis (EDC). Screws can be inserted in the standard midlateral position by retracting the brachioradialis (BR) tendon and the superficial radial nerve (SRN), in the dorsoradial position between the ECRL and ECRB or dorsally between the ECRB and EDC. Screw placement is done through a limited open approach to ensure identification and protection of the radial sensory and lateral antebrachial-cutaneous nerves. In non-bridging wrist applications, the distal screws must be applied in the safety zones between the extensor compartments dorsally and dorsoradially. In wrist bridging applications, the distal screws are applied into the second metacarpal bone, paying attention to the extensor tendon and the radiodorsal neuro-vascular bundle on the extensor and radiodorsal side. If the screws are placed too laterally, they will impede the function of the thumb. For this reason, an angle of 30-45° dorsally from the frontal plane is preferable.



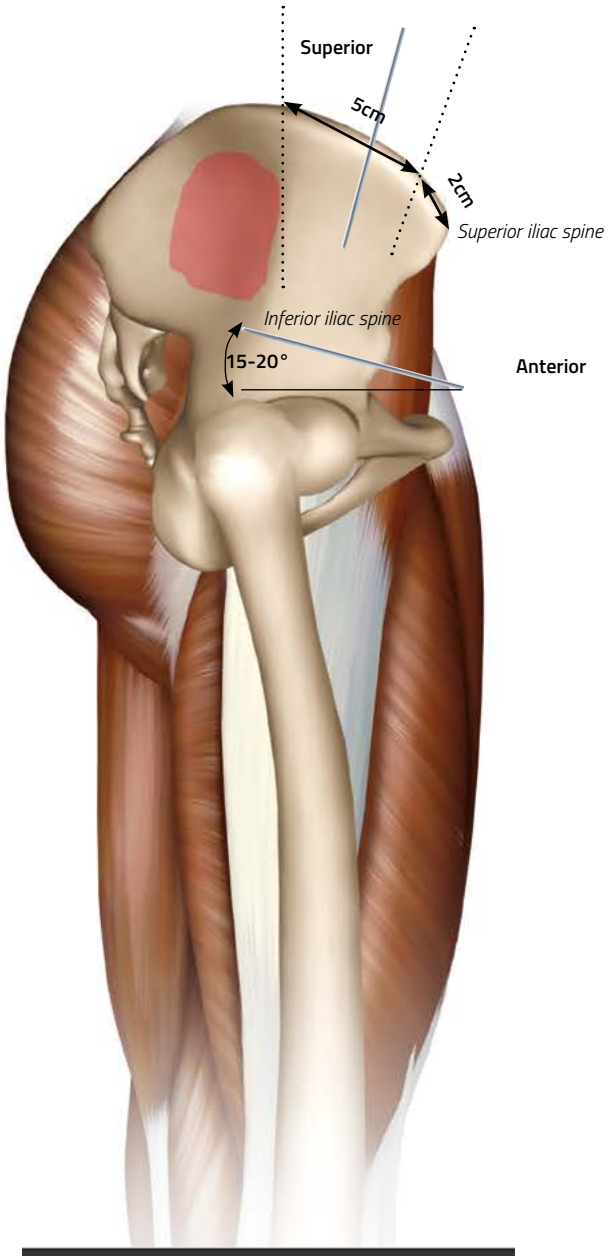
Pelvis

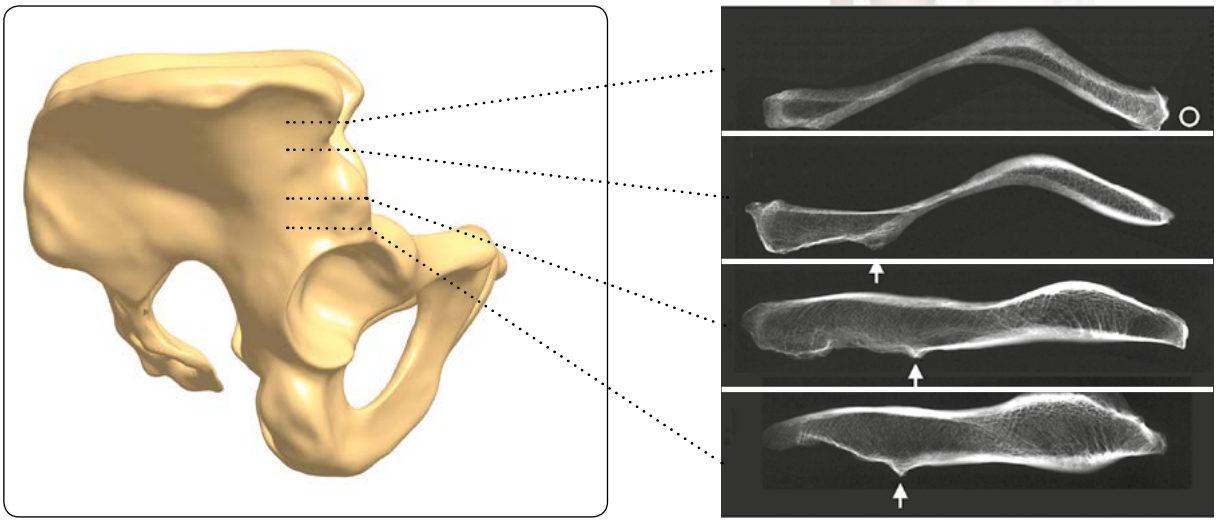
There are two recommended options for screw placement in the pelvis.

SUPRA-ACETABULAR (ANTERIOR) SCREW PLACEMENT
Given the wider cross sectional area and better bone purchase, the more technically difficult supraacetabular screw placement is preferred over that of the iliac crest. Proceeding from the anterior superior iliac spine, the site of entry is approximately 4-6cm in a caudal direction and 2-3cm in a medial direction. A skin incision of about 3-4cm is made and the subcutaneous tissue divided by blunt dissection to preserve the lateral cutaneous nerve of the thigh. The bone at the anterior inferior iliac spine is palpated and the screw guide placed firmly on the bone. The starting point is checked with an outlet-oburatory view and with an iliac view.

The anterior inferior iliac spine (AIIS) is drilled for 1cm, then screw is tapped into the bone and advanced gradually between the inner and outer cortical tables of the ilium, inclined about 15°-20° in a cranial direction and 30° internally. Check the direction of the screw with an iliac view and with an inlet-obturatory view. The end point is close to the sacroiliac joint and above the greater sciatic notch.

ILIAC CREST (SUPERIOR) SCREW PLACEMENT
To prevent damage to the lateral cutaneous nerve of the thigh, avoid insertion less than 20mm posterior to the anterior superior iliac spine. The iliac crest can easily be palpated. Adequate bone substance for screw insertion is only found in the anterior part of the iliac crest, from 2cm to 7cm posterior to the anterior superior iliac spine. The screws should be directed towards the acetabulum and should follow the route between the outer and inner table of the ilium. Check the direction of the screw with an obturatory view.





SCREW INSERTION IN UPPER AND LOWER LIMB

Screw positions should be planned with regard to zone of injury; often this may extend beyond the fracture lines visible on the X-ray. Further thought into possible future surgeries, including plastic surgery and internal fixation procedures, should be given. X-rays of the fracture in two planes should be available. Screws should be positioned for maximum mechanical stability in each bone segment, with bicortical purchase by the screw threads and with each pin as far apart in each segment as the fracture lines and neighboring joints allow. Insert two screws into each main fragment free-hand using the following technique:
1) Make a 15mm incision through skin and deep fascia. Use blunt dissection to reach the underlying bone **(Fig. 1)**.

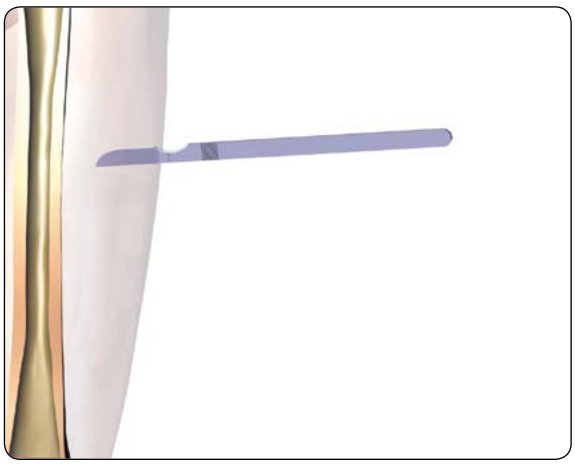


Fig. 1

2) Insert a screw guide perpendicular to the longitudinal axis of the bone. Use a trocar to locate the midline by palpation **(Fig. 2)**.

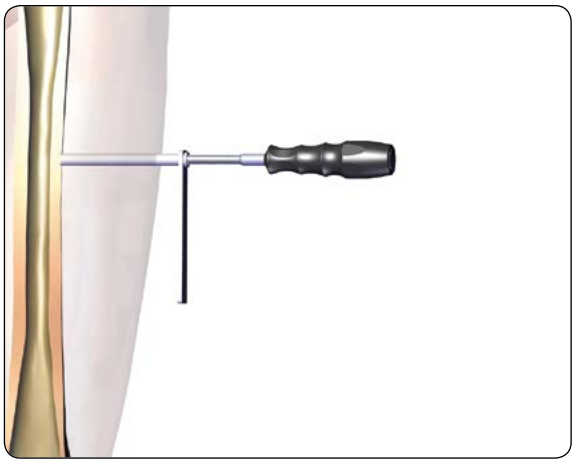


Fig. 2

3) Keeping the screw guide in contact with the cortex by gentle pressure, withdraw the trocar, and tap the screw guide lightly to anchor the pronged end against bone **(Fig. 3)**.

Fig. 3

When inserted after pre-drilling

Using the thread diameter, choose the proper drill bit and drill guide size and reference number according to the table below.

Bone screw Thread diameter	Drill Bit diameter	Drill Bit ref. number	Drill guide ref. number
6mm	4.8mm	1-1100201	11138
5mm	3.2mm	1-1100301	11106
4mm	3.2mm	1-1100301	11106

Insert the drill guide into the screw guide, and introduce a drill bit. Drill at 500-600 rpm through the first cortex, checking that the drill bit is at right angles to the bone. The force applied to the drill should be firm and the drilling time as short as possible to avoid thermal damage. Ensure that the drill bit completely penetrates the second cortex **(Fig. 4)**.

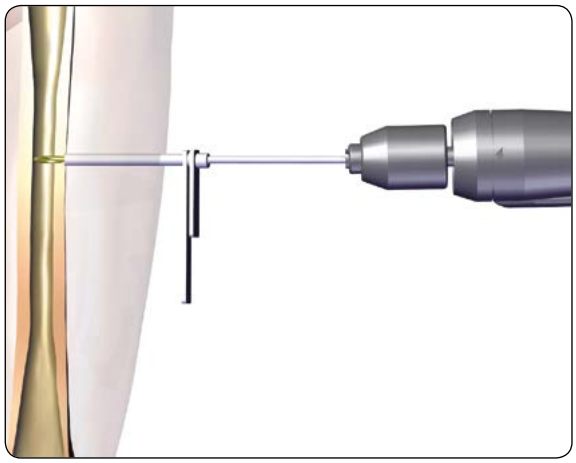


Fig. 4

Remove the drill bit and drill guide, keeping pressure on the handle of the screw guide. The screw is inserted with the T-Wrench QC or hand drill QC until it reaches the second cortex. Ensure that about 2mm of the screw protrudes beyond the second cortex **(Fig. 5)**.

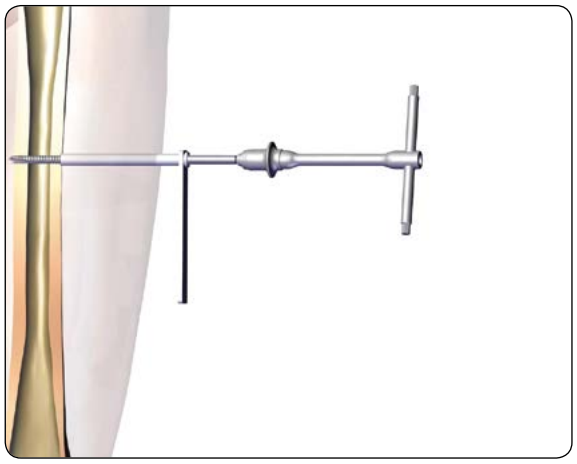


Fig. 5

When inserted with power drill

Insert a screw through the screw guide into the bone directly using the power drill. While drilling, the power drill should be held steady so that the drilling direction is maintained throughout the procedure. Once the second cortex has been reached, reduce the drilling speed.

Alternatively, a screw might be inserted manually with the hand drill QC or the T-wrench QC **(Fig. 6, 7)**. In diaphyseal bone, the screw should protrude 2mm beyond the distal cortex. In cancellous bone, there is no need for the screw to protrude from the second cortex.

In all cases the surgeon should be mindful of the amount of torque required to insert the screw. In general, it is advisable to pre-drill the diaphyseal bone using a drill bit.

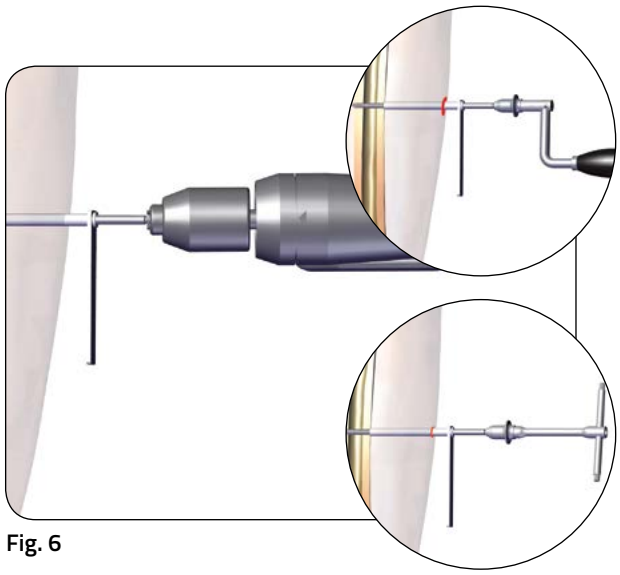


Fig. 6

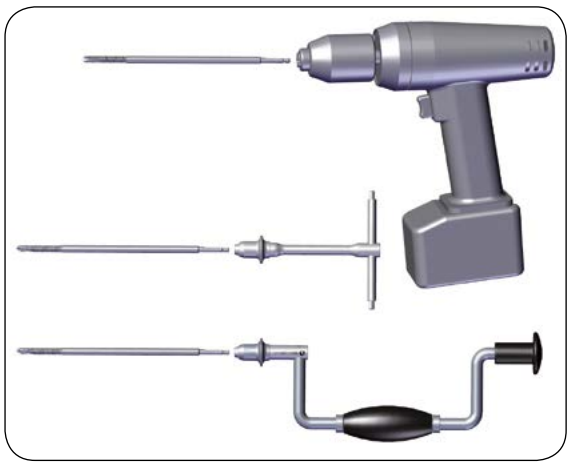


Fig. 7

When using a multipin clamp

Insert the first screw into one of the outer holes of the multi-screw clamp guide using the same technique as described above. Insert the second screw in the remaining outer seat and cut both screw shafts with the bone screw cutter. Lastly, insert the central screw if necessary.

Option 1
Use the multi-screw clamp as a template to insert screws perpendicular to the longitudinal axis of the bone **(Fig. 8a)**.

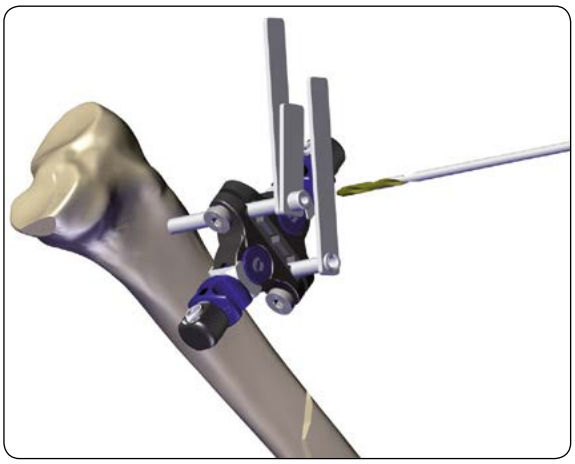


Fig. 8a

Option 2
Use the Multi-Screw Clamp Guide 194500 as a template to insert screws perpendicular to the longitudinal axis of the bone **(Fig. 8b)**.

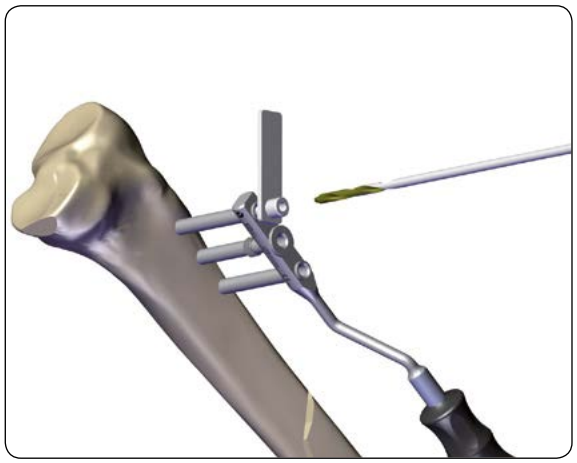


Fig. 8b

Cutting the Bone Screw Shafts to Length

When all screws have been inserted and the screw guides have been removed, the fixator is applied. After the fixator clamps have been securely locked over the screws, the screw shafts can be cut with the bone screw cutter. It is important that all of the screws are inserted first, and the fixator applied with the clamps tightened firmly over the screws, about 20mm from the skin. The cutter can then be slid over the screw shafts in turn and the screws cut close to the fixator clamps. This will normally result in about 6mm of screw shaft protruding from the fixator. The cut ends of the screws can then be protected with screw caps. When cutting the screws, the arms of the cutter should be extended for greater efficiency, and the outer end of the screw held to prevent it from causing injury **(Fig. 9)**. For bone screw removal, the T-Wrench QC has to be used. Alternatively, if the screws have been cut, the Universal T Wrench is necessary.

Fig. 9

XCaliber™ Cylindrical Bone Screw Design

The XCaliber Cylindrical Bone Screws have a pointed tip and flute **(Fig. 10)**, which allow them to be inserted self-drilling by using a power drill or a hand drill. The XCaliber Cylindrical Bone Screw threads have been designed to optimize insertion time and perforation of the second cortex. These screws can be backed out if not properly inserted without loosening the bone-screw interface. When insertion of a self-drilling XCaliber Cylindrical Bone Screw is performed in diaphyseal bone, pre-drilling might be recommended.

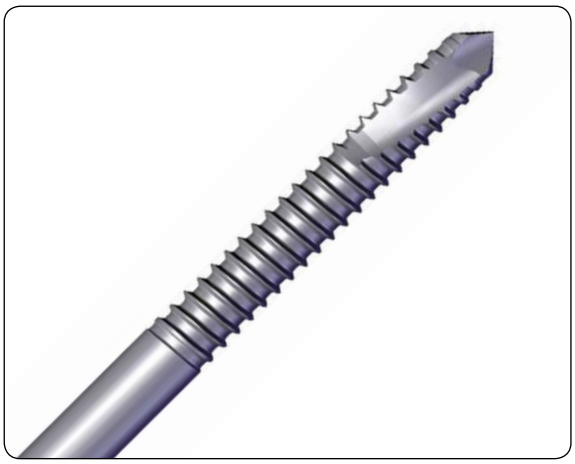


Fig. 10

EXAMPLE OF FRAME APPLICATION

Tibial Z-Frame

Tibial screws are preferentially inserted in the sagittal (anteroposterior) plane. Insert the remaining screws using the same technique **(Fig. 11)**.

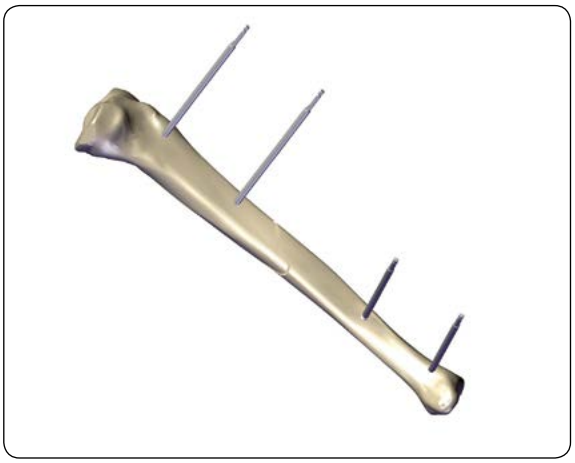


Fig. 11

Frame assembly

Instrumentation	
Part #	**Description**
30017	ALLEN WRENCH 5mm
or	
93162	T-WRENCH HEXAGON 5-5 QC

The two screws in each bone segment are joined by rods of suitable ength. Each one is mounted with two clamps positioned about 30mm from the skin **(Fig. 12)**.

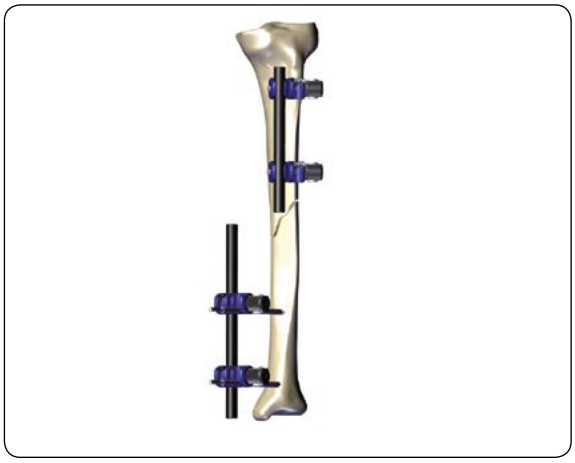


Fig. 12

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

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.

A third rod is then used to join the first two rods together by 2 more clamps, which are not yet tightened **(Fig. 13)**.

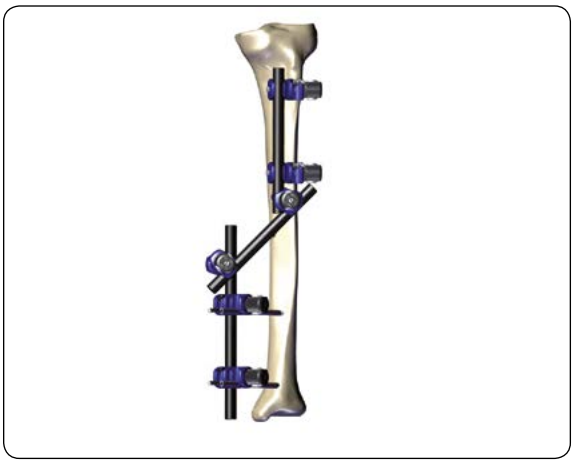


Fig. 13

WARNING: Depending on the clinical and radiological findings, the surgeon will decide on the number of rods and bone screws needed to achieve the appropriate frame stability.

The surgeon now manipulates the fracture, if possible under X-ray control. When the position is satisfactory, the assistant closes by hand tightening the remaining clamps **(Fig. 14a)** and then locks all the clamps firmly with the T-Wrench or the 5mm Allen Wrench **(Fig. 14b)**.

WARNING: Fracture stabilization has to be done following correct fracture reduction.

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

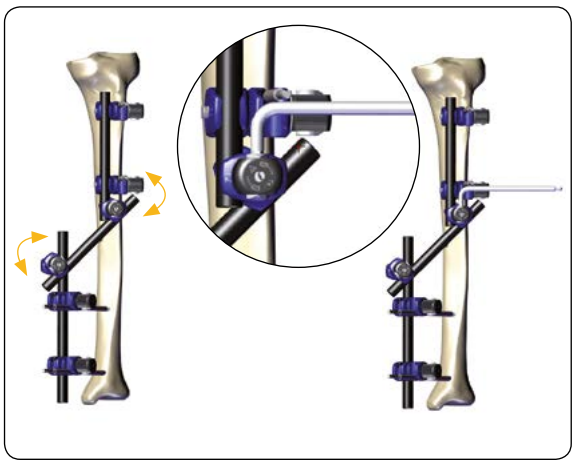


Fig. 14a **Fig. 14b**

Delta Frame Ankle Bridging

Screw insertion

Insert the 4mm self drilling transfixing pin in the medial aspect of the calcaneus, ensuring the entry point is away from the posterior tibial artery and nerve **(Fig. 15)**.

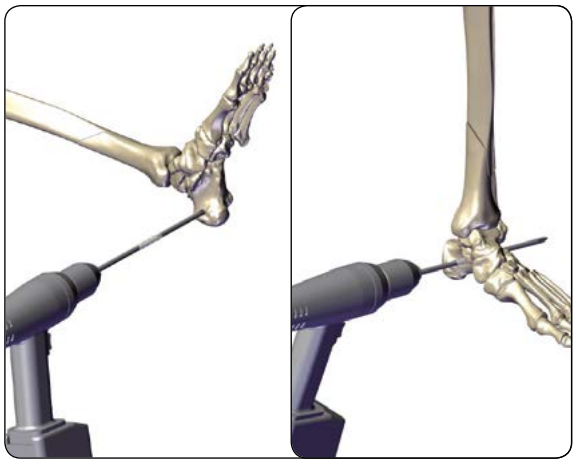


Fig. 15

The first tibial screw should be placed 1cm medial to the tibial crest in an anteroposterior direction. Use the trocar to locate the midline by palpation. Then insert the second tibial screw perpendicular to the longitudinal axis of the bone **(Fig. 16)**.

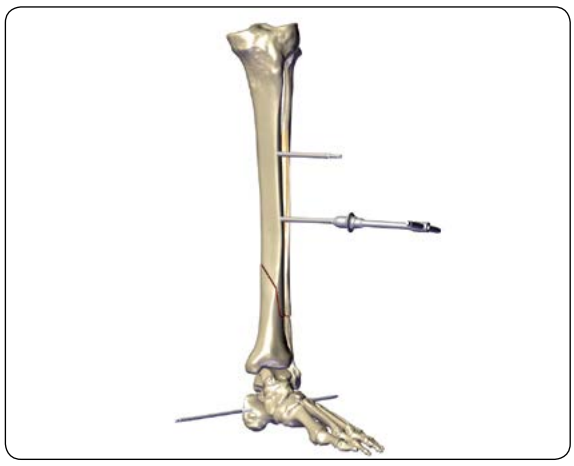


Fig. 16

Frame assembly

Instrumentation	
Part #	Description
30017	ALLEN WRENCH 5mm
or	
93162	T-WRENCH HEXAGON 5-5 QC

Connect the tibial bone screws with two clamps and 1 rod **(Fig. 17)**.

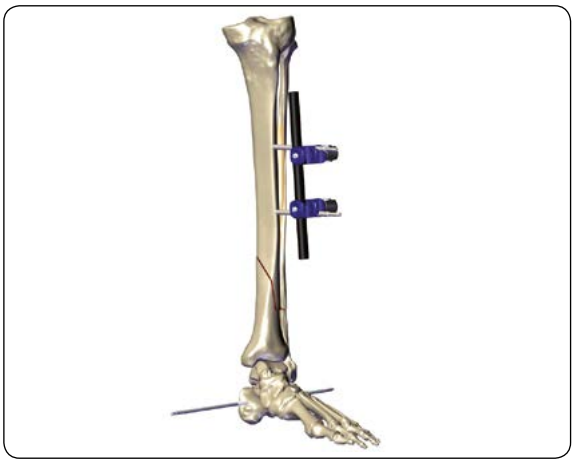


Fig. 17

Attach two clamps (one medial and one lateral) on the transfixing pin and connect them to the tibial rod or screws using two more rods and clamps. Ensure there is a sufficient length of rods on either side of proximal and distal clamps so as to enable reduction maneuvers **(Fig. 18)**. Reduce the fracture, close all the clamps by hand and tighten all clamps finally with the T-Wrench or the 5mm Allen Wrench **(Fig. 19)**.

WARNING: Fracture stabilization has to be done following correct fracture reduction.

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

WARNING: The clamp must be closed first manually by turning the knob clockwise before locking it firmly by tightening with the 5mm Allen Wrench.

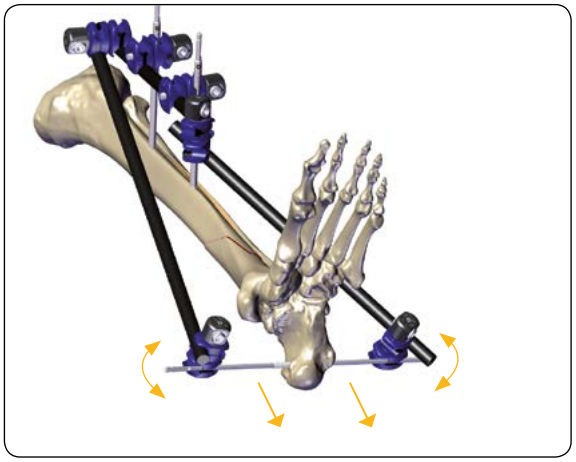


Fig. 18

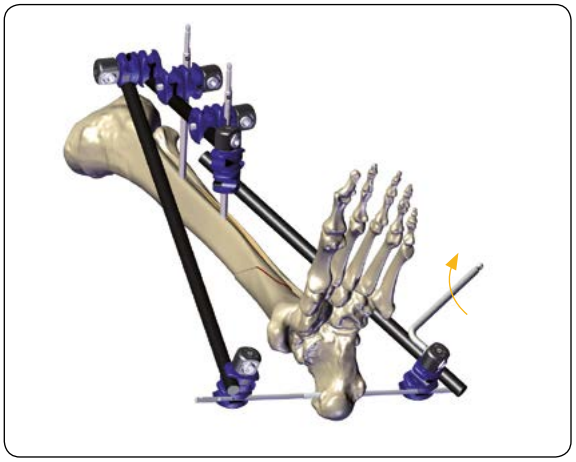


Fig. 19

If necessary, to avoid equinus deformity of the foot, insert a screw in the first metatarsal bone **(Fig. 20)** and connect it to the frame using additional clamps and rod **(Fig. 21)**.

WARNING: Depending on the clinical and radiological findings, the surgeon will decide on the number of rods and bone screws needed to achieve the appropriate frame stability.

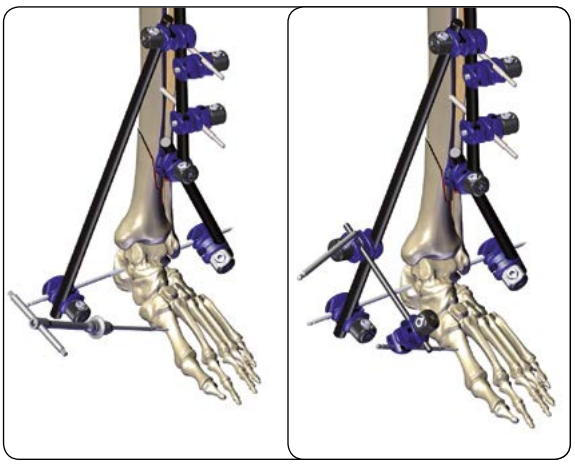
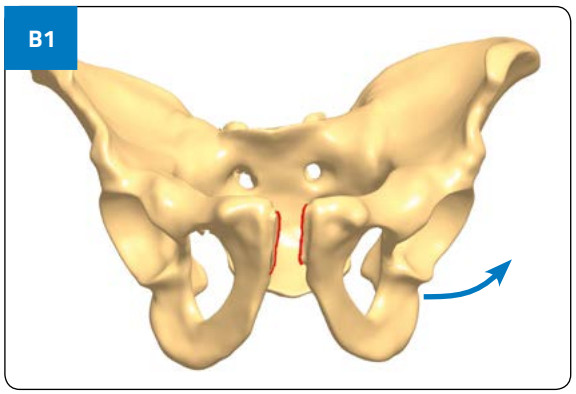


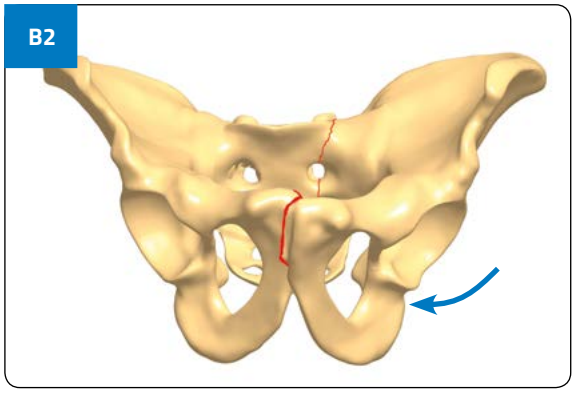
Fig. 20 Fig. 21

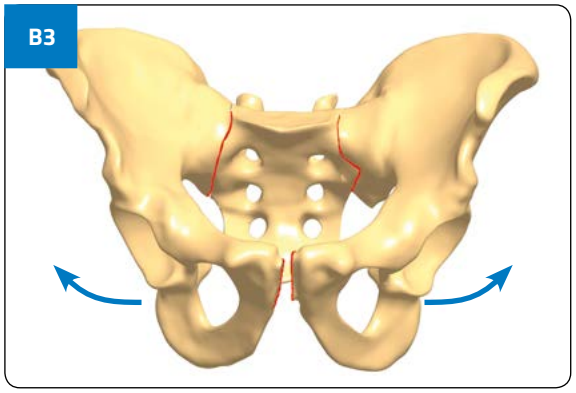
PELVIS FRACTURE TYPES

There are two main planes of instability: a horizontal plane and a vertical plane. Pelvic ring instability may be divided into three types according to Tile's classification, which indicate the type of management required. Type A injuries are stable and external fixation is therefore indicated only in Type B and C fractures to stabilize the anterior rotational instability. It is important to note that an anteriorly placed external fixator ONLY addresses this component of the instability; any component of the instability arising from posterior elements of the pelvic ring will require other methods of stabilization.

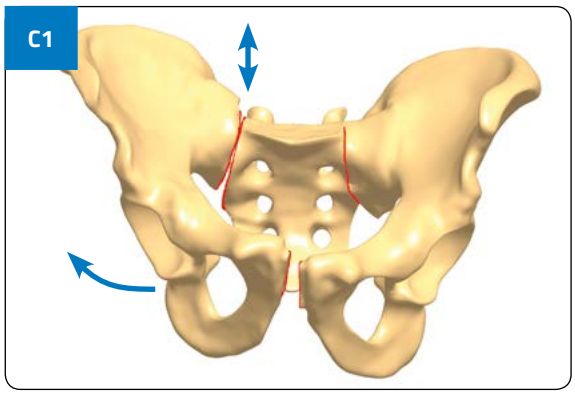
Type B - Rotationally unstable but vertically stable

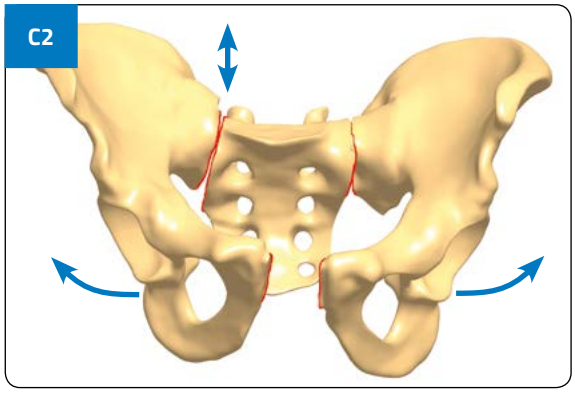


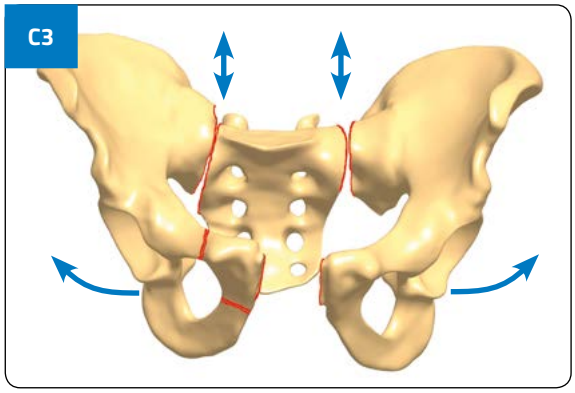




Type C - Rotationally and vertically unstable







In type B1 and B3 injuries a diastasis of the symphysis greater than 2.5cm indicates a severe rotational instability and an increased pelvic volume. An external fixator could be applied as an emergency procedure to reduce the pelvic volume and bleeding. However, the true instability in this “open book” fracture cannot securely be estimated by the AP X-ray. Clinical investigation (i.e. by testing stability manually) is mandatory for the indication of immediate external fixation. In type B2 injuries, external fixation is rarely necessary as an emergency procedure because the impaction of the fracture site leads to a sufficient stability and there is no increased pelvic volume. CT investigation may clarify the true fracture pattern and subsequently the correct treatment protocol, and is also recommended to evaluate the posterior structures (sacro-iliac joint, sacrum, posterior part of iliac bone). Type C injuries are always considered unstable. In an emergency situation the fixator is used on the anterior side of the pelvic ring with screws either in the supra- acetabular region and/or at the iliac crest to increase stability. The posterior part of the pelvic ring cannot be fully controlled by the external fixator. After resuscitation of the patient and further investigation, subsequent internal fixation of the posterior part of the pelvic ring may be considered.

SCREW INSERTION IN PELVIS

Part #	Description
11004	TAPERED TROCAR
93161	HAND DRILL QC
11102	SCREW GUIDE, L 60mm
	or
11137	SCREW GUIDE, L80mm
93162	T-WRENCH HEXAGON 5-5 QC
11106	DRILL GUIDE D 3.2mm L 40mm
1-1100301	DRILL BIT D 3.2mm L 200mm TIN COATED - QC

Start with the uninjured side. For supra acetabular screw placement, make an incision just caudal and medial to the anterior superior iliac spine to course over the anterior inferior iliac spine. Identify the lateral edge of Sartorius muscle and retract medially. The rounded tendinous portion of rectus femoris can be seen arising from the anterior inferior iliac spine. Make an incision down to bone just cranial to the spine. Roughen this area with a periosteal elevator. Tap a self-drilling screw 5-8mm into the roughened area in order to engage the bony cortex and advance the screw using turns of the T-Wrench. Aim the screw 15-20 degrees cranial to avoid penetration of the hip joint and to enter the widest part of the ilium above the greater sciatic notch **(Fig. 22)**. Check the advancement of the screw with the x-ray intensifier. For iliac wing screw placement you can usually palpate the wing. Make a 5 cm incision in the anterior part of the wing, detach the oblique aponeurosis and expose the bone. Insert two Kirschner Wires to establish the orientation of the hemi pelvis: one from the iliac crest along the inner table of the ilium and one along the outer table. Insert a self-drilling screw, gently tap it through the cortex and screw it home with the T-Wrench, without forcing the screw in any direction. The depth of insertion is 40-50mm (almost the entire thread length) **(Fig. 23)**. In case of hard bone you can use a 3.2mm drill bit and drill guide to penetrate the hard cortex to a depth of 1cm before inserting the screw. Screws in the iliac crest should be inserted in a region from 2cm to 7cm posterior to the anterior superior iliac spine. These screws should be directed towards the acetabulum and should follow the route between the outer and inner table of the ilium.

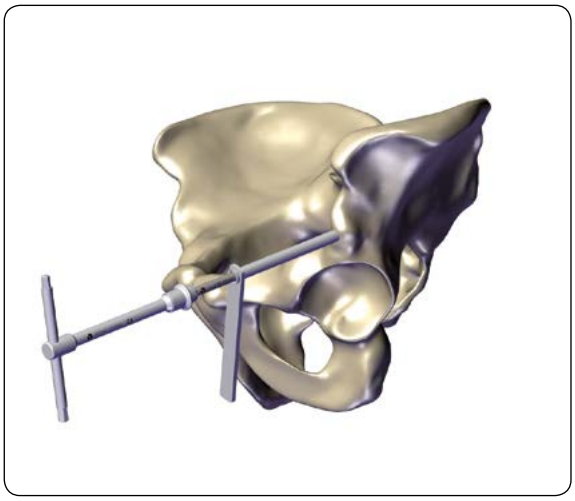


Fig. 22

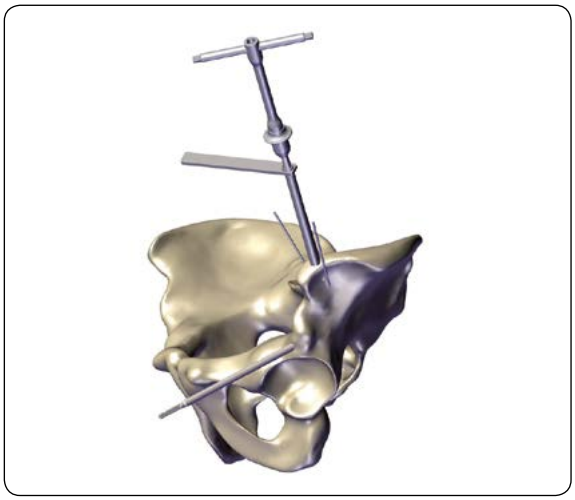


Fig. 23

EXAMPLE OF FRAME APPLICATION

Frame assembly

Instrumentation	
Part #	Description
30017	ALLEN WRENCH 5mm
	or
93162	T-WRENCH HEXAGON 5-5 QC

The two screws in each hemi pelvis are joined by rods of suitable length, each one mounted with 2 clamps. They are then locked manually by turning the knob clockwise. Two rods are then used to link the first two rods across the width of the pelvis through use of additional clamps that are attached but not yet tightened. The surgeon now manipulates the fracture, if possible under X-ray control. When the position is satisfactory, the assistant locks the clamps firmly by tightening clockwise with the T-Wrench or the 5mm Allen Wrench.

Warning: Fracture stabilization has to be done following correct fracture reduction.

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

Warning: Depending on the clinical and radiological findings, the surgeon will decide on the number of rods and bone screws needed to achieve the appropriate frame stability.

Warning: The clamp must be closed first manually by turning the knob clockwise before locking it firmly by tightening with the 5mm Allen Wrench.

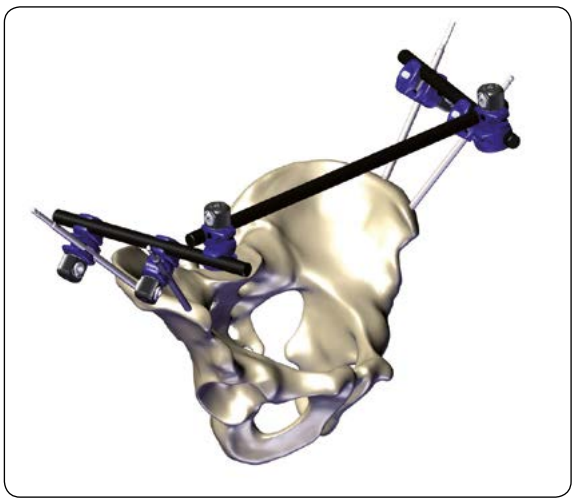


Fig. 24

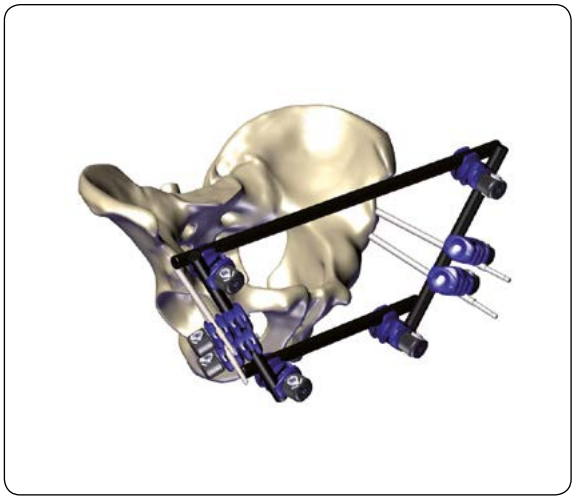


Fig. 25

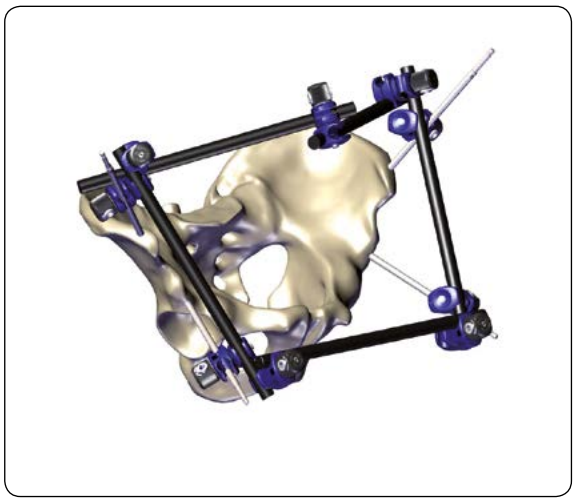
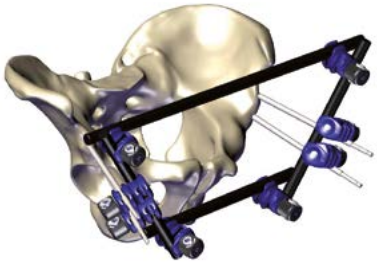


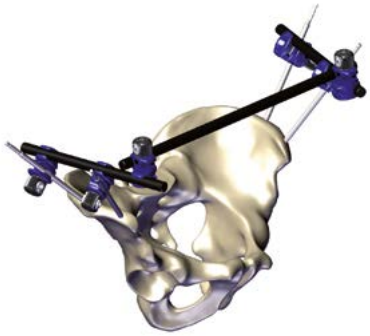
Fig. 26

POSSIBLE FRAME CONFIGURATIONS

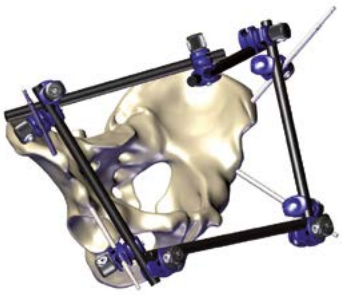
ANTERIOR APPLICATION



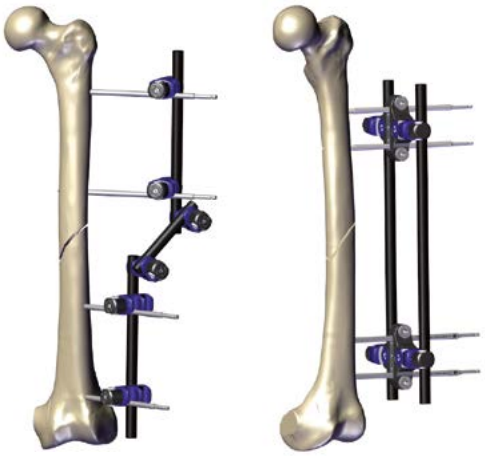
ILIAC CREST APPLICATION



HYBRID APPLICATION

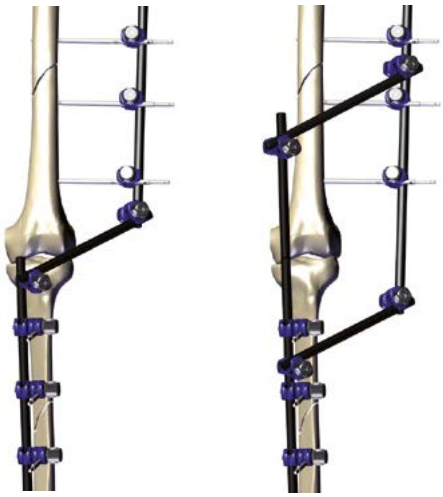


FEMUR



TIBIA

KNEE



HYBRID

ANKLE

HUMERUS

ELBOW

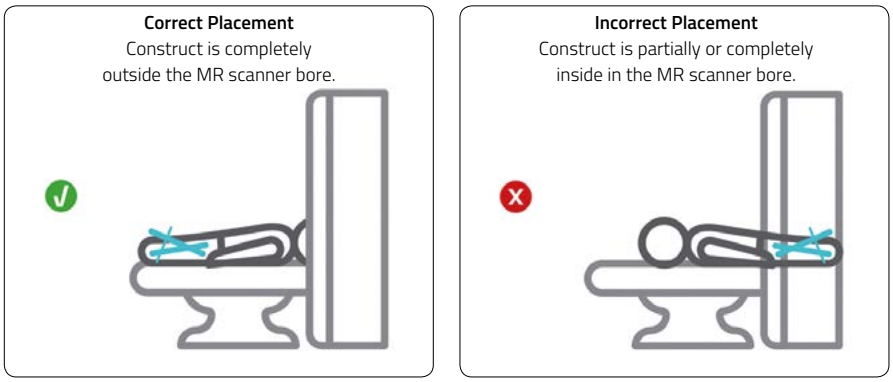
Frame Removal

Untighten the clamps by turning the drop back to the open position (12 o'clock) using the 30017 Allen Wrench or the T-Wrench hexagon 5-5 QC (93162). Then turn counterclockwise the knurled knob by hand. Disassemble the frame removing clamps and rods. Remove bone screws with AO Quick Connection manually with the T-Wrench hexagon 5-5 QC (93162). Remove bone screws that have been cut to length manually with the Universal T-Wrench (91150).

Instrumentation	
Part #	**Description**
93162	T-WRENCH HEXAGON 5-5 QC
	or
91150	UNIVERSAL T-WRENCH
30017	ALLEN WRENCH 5mm

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.



Outside the MRI bore MRI Safety Information A person with the GALAXY FIXATION may be safely scanned under the following conditions. Failure to follow these conditions may result in serious injury. CAUTION: All GALAXY FIXATION components must be outside the bore to avoid risk of excessive RF heating.	
Device Name	GALAXY FIXATION
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	GALAXY FIXATION components must not extend into the MRI bore. Therefore, MR scanning of body parts where the GALAXY FIXATION is located is contraindicated.

Non-clinical testing has demonstrated that the GALAXY FIXATION 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 Galaxy Fixation/Gemini 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 Galaxy Fixation/Gemini. From these studies, it is concluded that once the entire external fixation frame is visible outside the MRI bore, the maximum heating is less than 2°C. In non-clinical testing the worst scenarios produced the following temperature rises during MRI under the conditions reported above:

GALAXY FIXATION	**1.5Tesla System**	**3.0Tesla System**
Minutes of scanning	15	15
Calorimetry measured values, whole body averaged SAR (W/kg)	2.2W/Kg	2.5W/Kg
Highest temperature rise less than (°C)	2°C	2°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 Galaxy Fixation/Gemini Components are placed outside the MR bore.

Under the scan conditions defined above, the Galaxy Fixation™ Wrist Frames are expected to produce a maximum temperature rise of 1°C after 15 minutes of continuous scanning.

MR Patient Safety
MRI in patients with Galaxy Fixation/Gemini can only be performed under these parameters. Never scan the Galaxy Fixation/Gemini directly. Using other parameters, MRI could result in serious injury to the patient. When the Galaxy Fixation/Gemini 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. Galaxy Fixation/Gemini can only be guaranteed for MRI when using the following components to build a frame:

** The following components 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. 99-93030)*

RODS*

Part #	Description
932100	ROD 100mm LONG, 12mm DIAMETER
932150	ROD 150mm LONG, 12mm DIAMETER
932200	ROD 200mm LONG, 12mm DIAMETER
932250	ROD 250mm LONG, 12mm DIAMETER
932300	ROD 300mm LONG, 12mm DIAMETER
932350	ROD 350mm LONG, 12mm DIAMETER
932400	ROD 400mm LONG, 12mm DIAMETER
99-932450	ROD 450mm LONG, 12mm DIAMETER, STERILE**
99-932500	ROD 500mm LONG, 12mm DIAMETER, STERILE**
99-932550	ROD 550mm LONG, 12mm DIAMETER, STERILE**
99-932600	ROD 600mm LONG, 12mm DIAMETER, STERILE**
99-932650	ROD 650mm LONG, 12mm DIAMETER, STERILE**
939100	ROD 100mm LONG, 9mm DIAMETER
939150	ROD 150mm LONG, 9mm DIAMETER
939200	ROD 200mm LONG, 9mm DIAMETER
939250	ROD 250mm LONG, 9mm DIAMETER
939300	ROD 300mm LONG, 9mm DIAMETER
936060	ROD 60mm LONG, 6mm DIAMETER
936080	ROD 80mm LONG, 6mm DIAMETER
936100	ROD 100mm LONG, 6mm DIAMETER
936120	ROD 120mm LONG, 6mm DIAMETER
936140	ROD 140mm LONG, 6mm DIAMETER
936160	ROD 160mm LONG, 6mm DIAMETER
936180	ROD 180mm LONG, 6mm DIAMETER
936200	ROD 200mm LONG, 6mm DIAMETER

***** Special order only***

GALAXY FIXATION CLAMPS*

Part #	Description
93010	LARGE CLAMP
93110	MEDIUM CLAMP
93310	SMALL CLAMP
93020	MULTI-SCREW CLAMP
93030	LARGE-MEDIUM TRANSITION CLAMP
93120	MEDIUM MULTI-SCREW CLAMP
93040	LARGE DOUBLE MULTISCREW CLAMP
93140	MEDIUM DOUBLE MULTISCREW CLAMP

GALAXY FIXATION WRIST*

Part #	Description
93320	SMALL MULTI-SCREW CLAMP-LONG
93330	SMALL MULTI-SCREW CLAMP-SHORT
93350	WRIST MODULE

ELBOW HINGE*

Part #	Description
93410	ELBOW HINGE

GALAXY TL-HEX CONNECING POSTS*

Part #	Description
93031	GALAXY TL-HEX CONNECTING POST L50mm D12mm
93032	GALAXY TL-HEX CONNECTING POST L100mm D12mm

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XCALIBER CONICAL BONE SCREWS*

Part #	Shaft Ø	Thread Ø	Total L	Thread L
912630	6mm	6 - 5.6mm	260mm	30mm
912640	6mm	6 - 5.6mm	260mm	40mm
912650	6mm	6 - 5.6mm	260mm	50mm
912660	6mm	6 - 5.6mm	260mm	60mm
912670	6mm	6 - 5.6mm	260mm	70mm
912680	6mm	6 - 5.6mm	260mm	80mm
912690	6mm	6 - 5.6mm	260mm	90mm
911530	6mm	6 - 5.6mm	150mm	30mm
911540	6mm	6 - 5.6mm	150mm	40mm
911550	6mm	6 - 5.6mm	150mm	50mm
911560	6mm	6 - 5.6mm	150mm	60mm
911570	6mm	6 - 5.6mm	150mm	70mm
911580	6mm	6 - 5.6mm	150mm	80mm
911590	6mm	6 - 5.6mm	150mm	90mm

GEMINI CLAMPS*

Part #	Description
94100	GALAXY FIXATION GEMINI UNIVERSAL SINGLE CLAMP
94200	GGALAXY FIXATION GEMINI DOUBLE UNIVERSAL MUL-TIPIN CLAMP
94300	GALAXY FIXATION GEMINI UNIVERSAL MULTIPIN CLAMP
99-94010	GALAXY FIXATION GEMINI SINGLE CLAMP STERILE
99-94020	GGALAXY FIXATION GEMINI MULTIPIN CLAMP STERILE
99-94030	GALAXY FIXATION GEMINI TRANSITIONAL SINGLE CLAMP STERILE
99-94040	GALAXY FIXATION GEMINI DOUBLE MULTIPIN CLAMP STERILE
99-94140	GALAXY FIXATION GEMINI DOUBLE MULTIPIN CLAMP MEDIUM STERILE

BONE SCREWS*

Part #	Shaft Ø	Thread Ø	Total L	Thread L
10190	6mm	4,5 - 3.5mm	70	20
10191	6mm	4,5 - 3.5mm	80mm	20mm
10108	6mm	4,5 - 3.5mm	80mm	30mm
10135	6mm	4,5 - 3.5mm	100mm	20mm
10136	6mm	4,5 - 3.5mm	100mm	30mm
10105	6mm	4,5 - 3.5mm	100mm	40mm
10137	6mm	4,5 - 3.5mm	120mm	20mm
10138	6mm	4,5 - 3.5mm	120mm	30mm
10106	6mm	4,5 - 3.5mm	120mm	40mm
35100	4mm	3.3 - 3mm	70mm	20mm
35101	4mm	3.3 - 3mm	80mm	35mm
M310	3mm	3-2.5mm	50mm	18mm
M311	3mm	3-2.5mm	60mm	20mm
M312	3mm	3-2.5mm	60mm	25mm
M313	3mm	3-2.5mm	60mm	30mm
M321	3mm	3-2.5mm	70mm	15mm
M314	3mm	3-2.5mm	70mm	20mm
M315	3mm	3-2.5mm	70mm	25mm
M316	3mm	3-2.5mm	70mm	30mm
M317	3mm	3-2.5mm	100mm	30mm

TRANSFIXING PINS*

Part #	Description
1-92050	SS TRANSFIXING PIN L 260mm D 4mm THREAD D 5XL50mm QC
1-92080	SS TRANSFIXING PIN L 260mm D 4mm THREAD D 5XL80mm QC
1-93050	TRANSFIX PIN 50mm QC
1-93080	TRANSFIX PIN 80mm QC

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

XCALIBER CYLINDRICAL BONE SCREWS*				
Part #	Shaft Ø	Thread Ø	Total L	Thread L
942535	6mm	5mm	260mm	35mm
942540	6mm	5mm	260mm	40mm
942545	6mm	5mm	260mm	45mm
942550	6mm	5mm	260mm	50mm
942560	6mm	5mm	260mm	60mm
942570	6mm	5mm	260mm	70mm
942580	6mm	5mm	260mm	80mm
942590	6mm	5mm	260mm	90mm
944540	6mm	5mm	150mm	40mm
943420	6mm	4mm	100mm	20mm
943430	6mm	4mm	100mm	30mm
943440	6mm	4mm	100mm	40mm
944420	6mm	4mm	120mm	20mm
944430	6mm	4mm	120mm	30mm
944440	6mm	4mm	120mm	40mm
945420	6mm	4mm	150mm	20mm
945425	6mm	4mm	150mm	25mm
945430	6mm	4mm	150mm	30mm
945435	6mm	4mm	150mm	35mm
945440	6mm	4mm	150mm	40mm
946420	6mm	4mm	180mm	20mm
946430	6mm	4mm	180mm	30mm
946440	6mm	4mm	180mm	40mm
947320	6mm	4mm	100mm	20mm
947325	6mm	4mm	100mm	25mm
948315	4mm	3mm	120mm	15mm
948320	4mm	3mm	120mm	20mm
948325	4mm	3mm	120mm	25mm
948330	4mm	3mm	120mm	30mm
948335	4mm	3mm	120mm	35mm

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TL-HEX GALAXY FIXATION Hybrid System
The TL-HEX GALAXY FIXATION Hybrid System has not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. It has not been tested for heating, migration, or image artifact
in the MR environment. The safety of the TL-HEX GALAXY FIXATION Hybrid System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

TrueLok 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

TrueLok EVO Components	
Part #	**Description**
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

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions 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 +39045 6719301, fax +39045 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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