OPERATIVE TECHNIQUE

Galaxy Fixation™

System

Lower Extremities

ORTHOFIX®
ORTHOPEDICS

Galaxy Fixation™

System

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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.

Operative Technique Contributing Surgeons:

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INTRODUCTION AND INDICATIONS

External fixators have become multi-function devices with indications for use in trauma and Orthopaedics. Trauma applications include damage control or definitive treatment of injuries whereas Orthopaedic applications have included reconstructive surgery. The Galaxy Fixation™ System (Galaxy Fixation System hereinafter) is designed to provide the multi-function capabilities of an external fixator for modern trauma and reconstructive surgery. The components have been designed for rapid application, stability and ease of use. The modules of the Galaxy Fixation System have a consistency of design across the range of trauma and reconstructive modules. This ensures that surgeons can become accustomed to the entire range quickly. Additionally, the system encompasses the facility for use in small and large long bones and extends to cover adult and paediatric applications. This wide capability has been designed with stability as a primary system characteristic.
In so doing, the surgeon can:

- place screws where the condition of the bone and soft tissues permits
- reduce the fracture or joint to restore alignment easily
- achieve stability with the efficient use of bone screws, rods and clamps (examples of fixator configurations that provide stability through optimal use components are provided and thereby contribute to standardisation of use)

For **"MRI information" see page 28**.

The rods and bone screws are strictly single patient use.

FEATURES AND BENEFITS

Rods

Strong radiolucent rods in three different diameters (12mm for Lower Limb, 9mm and 6mm for Upper Limb) and various lengths.

Rods **Diameter 12mm**

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

*** Special order only**

Rods **Diameter 9mm**

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

Rods **Diameter 6mm**

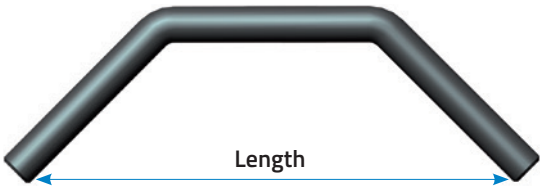
Part #	Description
936060	Rod 60mm L
936080	Rod 80mm L
936100	Rod 100mm L
936120	Rod 120mm L
936140	Rod 140mm L
936160	Rod 160mm L
936180	Rod 180mm L
936200	Rod 200mm L

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

L Rod **Diameter 6mm**

Part #	Description
936010	6mm L Rod

Semi-Circular Rods (Aluminum) **Diameter 12mm**



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

Semi-Circular Rods **Diameter 9mm**

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

Screws

XCaliber™ Bone Screws Shaft Ø 6mm - Thread Ø 6.0-5.6mm

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

- Drill bit Ø 4.8mm when the bone is hard
- Drill bit Ø 3.2mm in poor quality bone or in the metaphyseal region

Bone Screws Shaft Ø 6mm - Thread Ø 4.5-3.5mm

Part #	Total L	Thread L	Part #	Total L	Thread L
10190	70	20	**10105**	100	40
10191	80	20	**10137**	120	20
10108	80	30	**10138**	120	30
10135	100	20	**10106**	120	40
10136	100	30			

- Drill bit Ø 3.2mm

Bone Screws Shaft Ø 4mm - Thread Ø 3.3-3.0mm

Part #	Total L	Thread L	Part #	Total L	Thread L
35100	70	20	**35101**	80	35

- Drill bit Ø 2.7mm

Self-drilling Bone Screws Shaft Ø 4mm - Thread Ø 3.3-3.0mm

Part #	Total L	Thread L	Part #	Total L	Thread L
37100	60	20	**37101**	70	30
37102	100	30			

Self-drilling Bone Screws Shaft Ø 3mm - Thread Ø 3.0-2.5mm

Part #	Total L	Thread L	Part #	Total L	Thread L
M310	50	18	**M314**	70	20
M311	60	20	**M315**	70	25
M312	60	25	**M316**	70	30
M313	60	30	**M317**	100	30
M321	70	15			

XCaliber™ Cylindrical Bone Screws Shaft Ø 4mm - Thread Ø 3.0mm

Part #	Total L	Thread L	Part #	Total L	Thread L
948320	120	20	**947320**	100	20
948325	120	25	**947325**	100	25
948335	120	35			

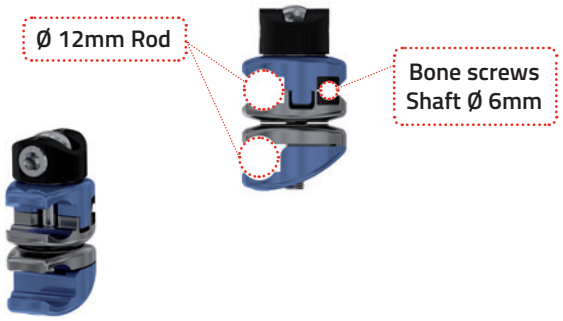
- Self-drilling

Galaxy Fixation™ 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.

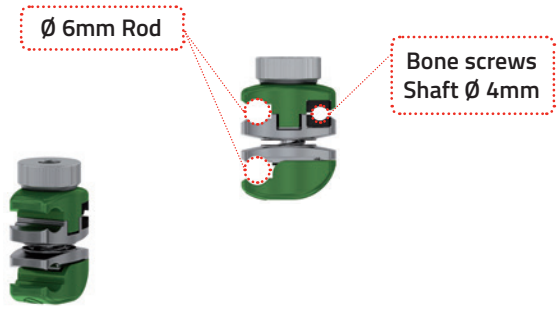
Clamps for Independent Screw Placement

Allow easy and stable connection of either a rod and a bone screw or two rods.

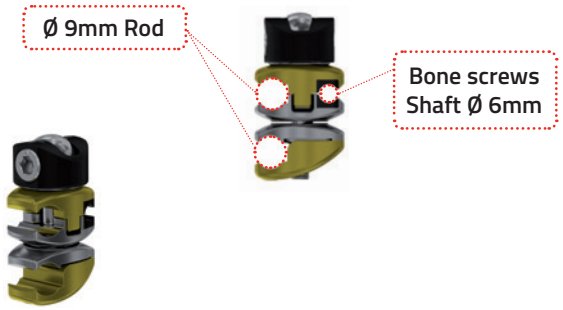
Large Clamp (93010)



Small Clamp (93310)

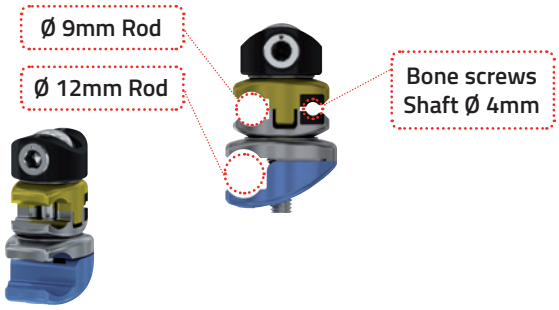


Medium Clamp (93110)

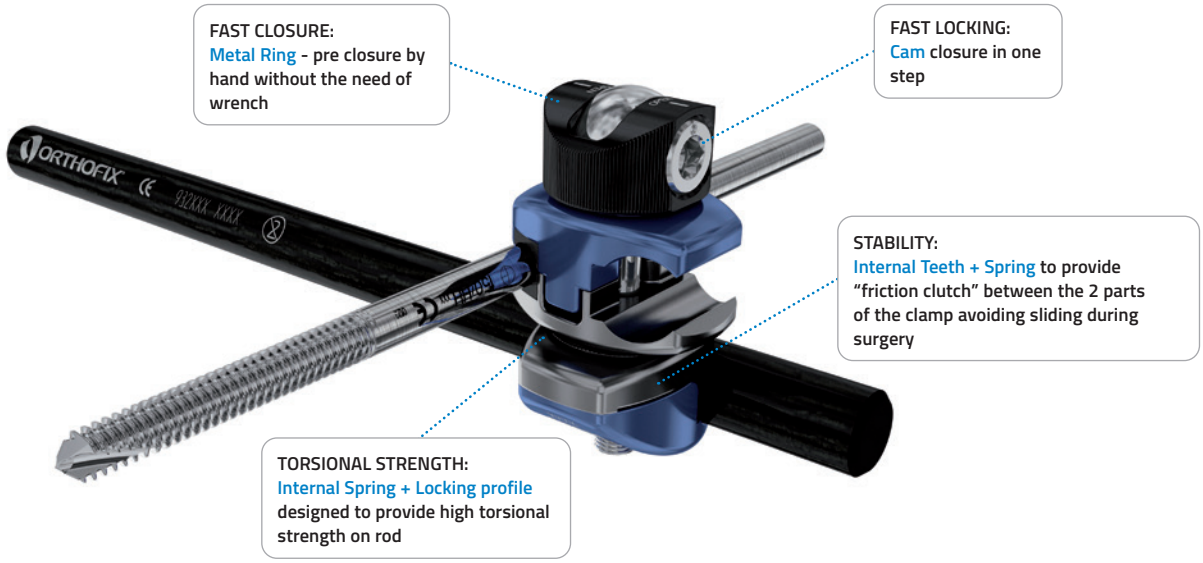


Galaxy Line Extension

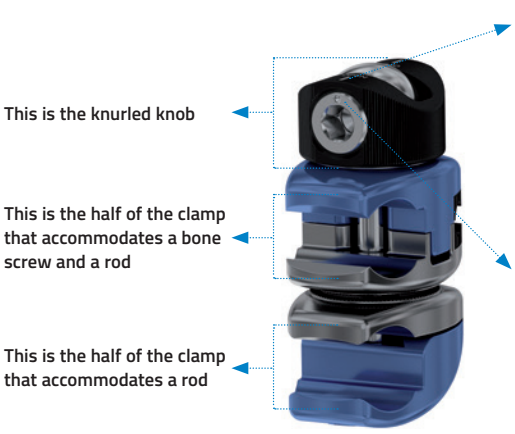
Large-Medium Transition Clamp (99-93030) (Sterile)

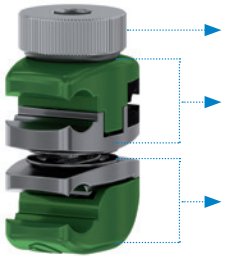


Simple: one clamp for rod-to-rod and pin-to-rod connections
Easy: snap-in system, provisional tightening by hand, definitive cam closure in one step
Versatile: sterile kits for each anatomical site, sterile single-packed components, instrument and implant trays
Stable: internal teeth and locking profiles designed to provide high torsional strength and avoid components sliding
MRI conditional at 1.5 and 3 Tesla



CLAMP CLOSURE PROCEDURES

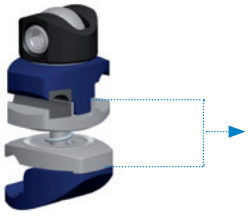




1 FRAME ASSEMBLY

Start position - Clamp open

The dot on the bolt must be in line with the "OPEN" marking on the metal ring (12 o'clock)



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

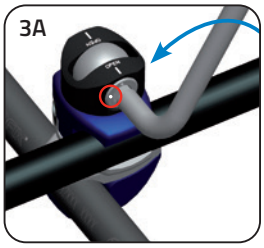
2 PRELIMINARY CLOSURE AND FRACTURE REDUCTION

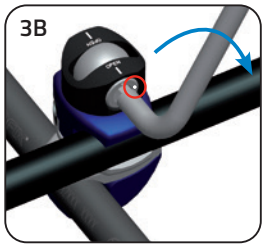
Pre-closure by hand

The dot on bolt must be kept in line with the "OPEN" marking on the metal ring (12 o'clock), while the knurled knob is turned by hand clockwise

The two halves of the clamp are now tightened closed; rods and bone screws cannot be inserted anymore

3 DEFINITIVE FRAME LOCKING



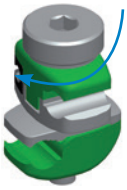


Final closure

The 5mm Allen Wrench is inserted in the bolt and is turned either clockwise (3 o'clock - **3B**) or counter clockwise (9 o'clock - **3A**). This engages a cam for final tightening

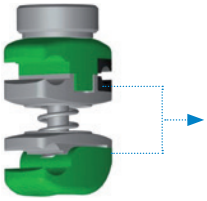
Now the dot on cam has moved accordingly

1 FRAME ASSEMBLY



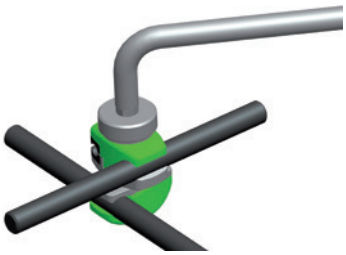
Pre-Closure

Turn the locking screw fully by hand



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

2 FINAL CLOSURE



Tighten the locking screw with Allen Wrench

The two halves of the clamp are now tightened closed; rods and bone screws cannot be inserted anymore

Multi-Screw Clamp (93020) MR

- To be used with 12mm rod and 6mm shaft bone screws.
- Allows parallel screw positioning either in a T- or a straight clamp configuration.

The positions of the screw holes in the multi-screw clamp refer to the screw seats of the XCaliber Fixator or the 1,3,5 screw seats of the LRS Fixator T- or straight clamps.

STABILITY:
Internal Spring + Locking profile designed to provide high torsional strength on rod

FAST LOCKING:
Cam closure in one step

FLEXIBILITY OF USE:
Rotation up to +/- 35°

FAST INSERTION:
Snap Lock

FAST CLOSURE:
Metal Ring - pre closure by hand without the need of wrench

Galaxy Line Extension

Medium Multi-Screw Clamp (99-93120) (Sterile) MR

Allows parallel screw positioning (+/- 35°) in either a T-clamp or straight clamp configuration

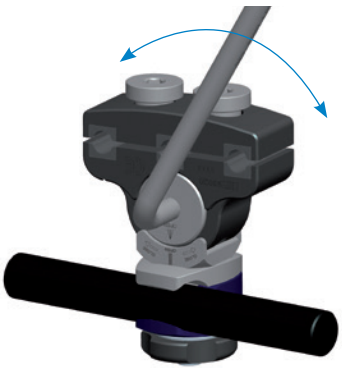
The positions of the screw holes in the medium screw clamp refer to the screw seats of the Small Blue D.A.F. (31000) or the pediatric LRS system (series 55000)

1

Start Position
Dot on cam in line with OPEN marking on the base of the clamp

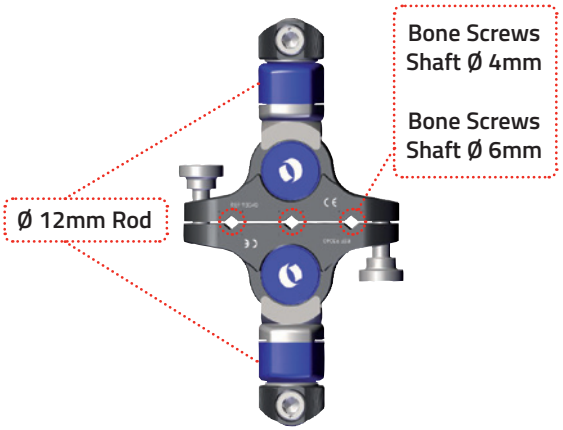
2 **Pre-Closure**
Turn the the knob fully by hand

3 **Final Closure**
Tighten the cam with Allen Wrench

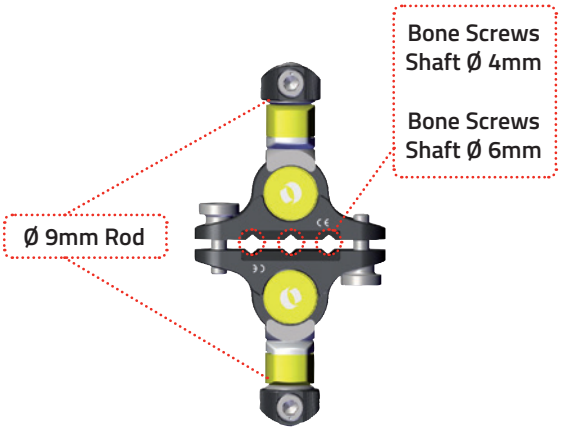


Double Multi-screw Clamps

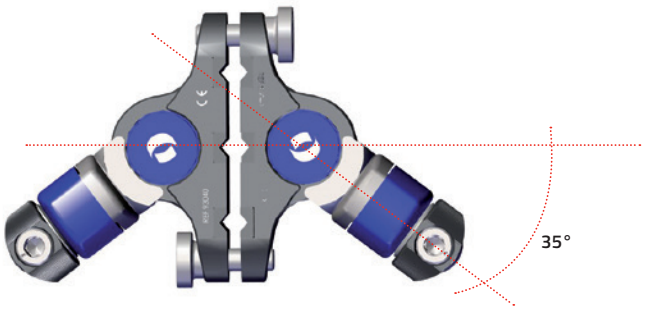
Double Multi-screw Clamp Large MR
(99-93040)



Double Multi-screw Clamp Large MR
(99-93040)



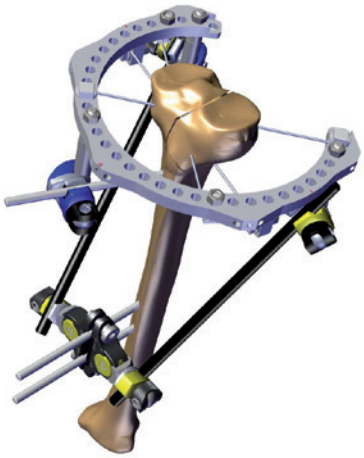
All clamps are also available single-packed and sterile.
They can be ordered using the above part numbers preceded by 99- (e.g. 99-93010)



GALAXY FIXATION™ / TL-HEX™ CONNECTION SYSTEM

Tibia

Tibia



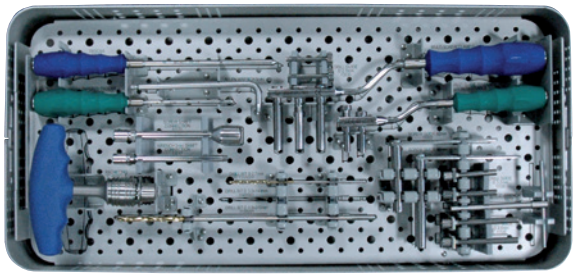
Galaxy TL-HEX Connecting Post

Part #	Description
93031	Galaxy TL-HEX Connecting Post L 50mm D12mm
93032	Galaxy TL-HEX Connecting Post L100mm D12mm

EQUIPMENT REQUIRED

93992 - GALAXY instruments empty tray
can accommodate:

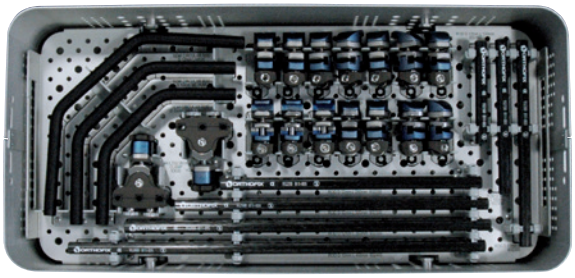
Part #	Description
19940	Multi-screw Clamp Guide
11138	Drill Guide d 4.8mm
11137	Screw Guide 80mm
1-1100201	Drill Bit d 4.8x240mm Coated - Quick Connect
11106	Drill Guide d 3.2mm
11102	Screw Guide 60mm
1-1300301	Drill Bit d 3.2x140mm Coated - Quick Connect
19955	Trocar
19960	Wrist Guide Template with Handle
13530	Drill Guide d 2.7mm
1-1355001	Drill Bit d 2.7x127mm Coated - Quick Connect
19965	Tapered Trocar
M210	T Wrench
93150	Racheting T Handle
93155	Screw Shaft Connection
30017	Allen Wrench 5mm
93017	Wrench 5mm Shaft Connection

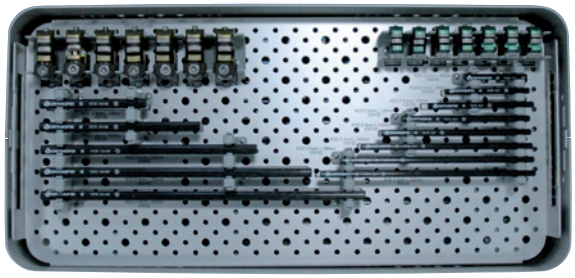


93991 - GALAXY upper & lower empty tray*
can accommodate:

Part #	Description
Lower Tray	
93010	Large Clamp
93020	Multi-screw Clamp
932400	Rod d 12mm L 400mm
932350	Rod d 12mm L 350mm
932300	Rod d 12mm L 300mm
932250	Rod d 12mm L 250mm
932200	Rod d 12mm L 200mm
932150	Rod d 12mm L 150mm
932100	Rod d 12mm L 100mm
932030	Semi Circular Rod d 12mm large
932020	Semi Circular Rod d 12mm medium
932010	Semi Circular Rod d 12mm small
Upper Tray	
93110	Medium Clamp
93310	Small Clamp
939300	Rod d 9mm L 300mm
939250	Rod d 9mm L 250mm
939200	Rod d 9mm L 200mm
939150	Rod d 9mm L 150mm
939100	Rod d 9mm L 100mm
936200	Rod d 6mm L 200mm
936180	Rod d 6mm L 180mm
936160	Rod d 6mm L 160mm
936140	Rod d 6mm L 140mm
936120	Rod d 6mm L 120mm
936100	Rod d 6mm L 100mm
936080	Rod d 6mm L 80mm
936060	Rod d 6mm L 60mm

*** to order any of the Rods or Clamps, single-packed and sterile, please add 99- prior to the part number, ex. 99-93010**





TRAY CONFIGURATION

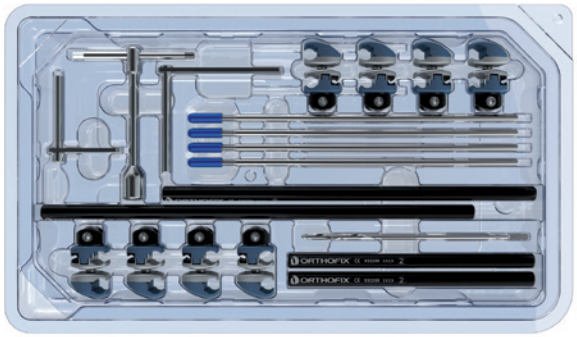
Part #	Description
93993	GALAXY LOWER & INSTRUMENTS EMPTY TRAY
93994	GALAXY UPPER & INSTRUMENTS EMPTY TRAY
93995	GALAXY UPPER EMPTY TRAY
93996	GALAXY LOWER EMPTY TRAY

Sterile Kit

Besides the sterile pre-packaged kits, Galaxy Fixation System offers all **clamps and rods pre-packaged and sterile individually**. They can be ordered using the part number preceded by 99- (e.g. 99-939300).

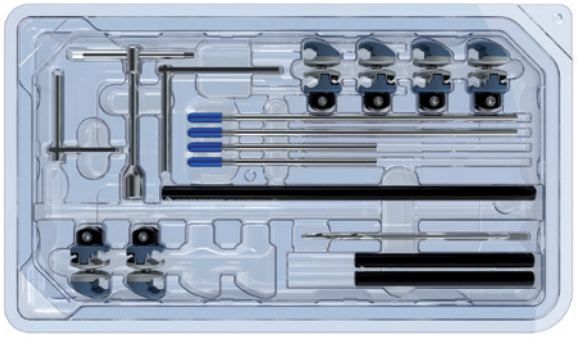
99-93501 - Pelvis Sterile Kit
consisting of:

Part #	Description	Qty
93010	Large Clamp	8
932350	Rod d 12mm L 350mm	1
932300	Rod d 12mm L 300mm	1
932200	Rod d 12mm L 200mm	2
912640	Self-drilling XCaliber Screws, L 260mm, thread L 40mm	4
11138	Drill Guide d 4.8mm	1
11137	Screw Guide 80mm	1
1-1100101	Drill Bit d 4.8x180mm Coated - Quick Connect	1
91150	Bone Screw T Wrench	1



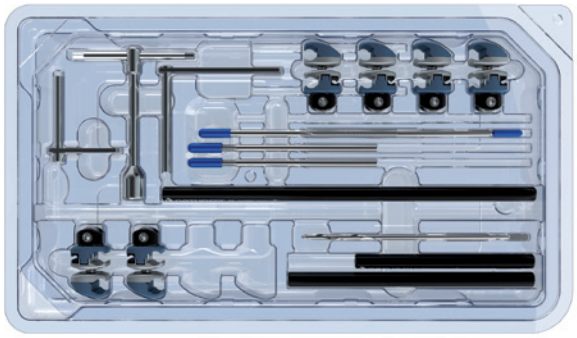
99-93502 - Lower Limb Diaphyseal Sterile Kit
consisting of:

Part #	Description	Qty
93010	Large Clamp	6
932300	Rod d 12mm L 300mm	1
932150	Rod d 12mm L 150mm	2
912650	Self-drilling XCaliber Screws, L 260mm, thread L 50mm	2
911550	Self-drilling XCaliber Screws, L 150mm, thread L 50mm	2
11138	Drill Guide d 4.8mm	1
11137	Screw Guide 80mm	1
1-1100101	Drill Bit d 4.8x180mm Coated - Quick Connect	1
91150	Bone Screw T Wrench	1



99-93503 - Ankle Sterile Kit
consisting of:

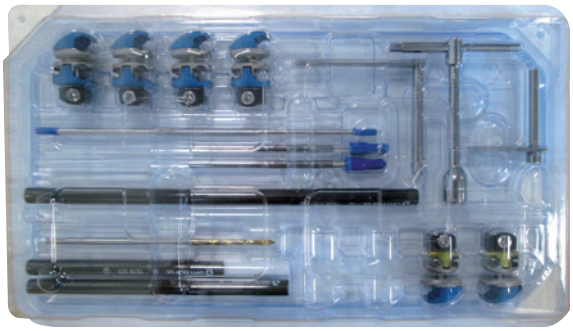
Part #	Description	Qty
93010	Large Clamp	6
932300	Rod d 12mm L 300mm	1
932200	Rod d 12mm L 200mm	1
932150	Rod d 12mm L 150mm	1
911540	Self-drilling XCaliber Screws, L 150mm, thread L 40mm	2
11138	Drill Guide d 4.8mm	1
11137	Screw Guide 80mm	1
1-1100101	Drill Bit d 4.8x180mm Coated - Quick Connect	1
91150	Bone Screw T Wrench	1
93080	Transfix Pin 80mm - Shaft d 6mm/ Thread d 7mm	1



99-93499 - Ankle Sterile kit - Transfix Pin Ø 4mm

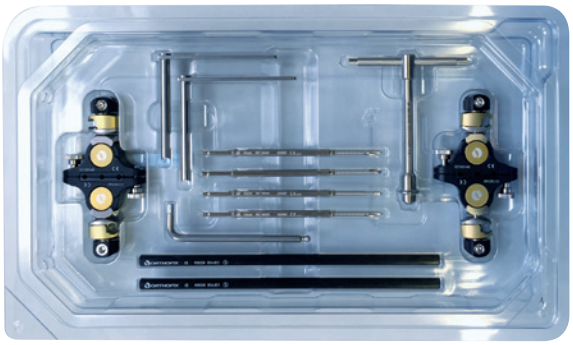
can accommodate:

Part #	Description	Qty
93010	Large Clamp	4
93030	Transitional Clamp	2
932300	Rod d 12mm L 300mm	1
932200	Rod d 12mm L 200mm	1
932150	Rod d 12mm L 150mm	1
911540	XCaliber Screws	2
11138	Drill Guide d 4.8mm	1
11137	Screw Guide 80mm	1
1-1100101	Drill Bit d 4.8x180mm	1
91150	Universal "T" Wrench	1
92080	Transfix Pin thread L 80mm, thread Ø 5mm, shaft 4mm	1



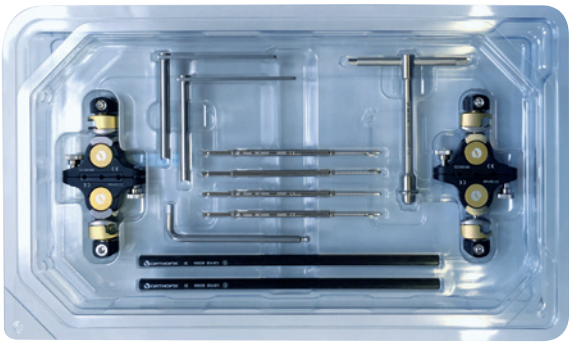
99-93520 - Galaxy Medium - Paediatric Sterile Kit - Ø 5mm screw thread

Part #	Description	Qty
93140	Double multipin clamp medium	2
939250	Rod d 9mm L 250mm	2
944540	Selfdrilling XCaliber Cylindrical Screw shaft Ø 6mm thread 5mm L 150/40QC	4
11137	Screw Guide 80mm	2
30017	Allen Wrench 5mm	1
93160	QC Wrench	1



99-93521 - Galaxy Medium - Paediatric Sterile Kit - Ø 4mm screw thread

Part #	Description	Qty
93140	Double multipin clamp medium	2
939250	Rod d 9mm L 250mm	2
944530	Selfdrilling XCaliber Cylindrical Screw shaft Ø 6mm thread 4mm L 150/30QC	4
11137	Screw Guide 80mm	2
30017	Allen Wrench 5mm	1
93160	QC Wrench	1



GENERAL INSTRUCTIONS

Screw Insertion

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. In general, screws should be placed anterolaterally in the femur; anteriorly (1cm medial to the tibial crest in an anteroposterior direction) in the tibia; laterally in the proximal third of humerus and posterolaterally in the distal third of the humerus. 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)**.

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

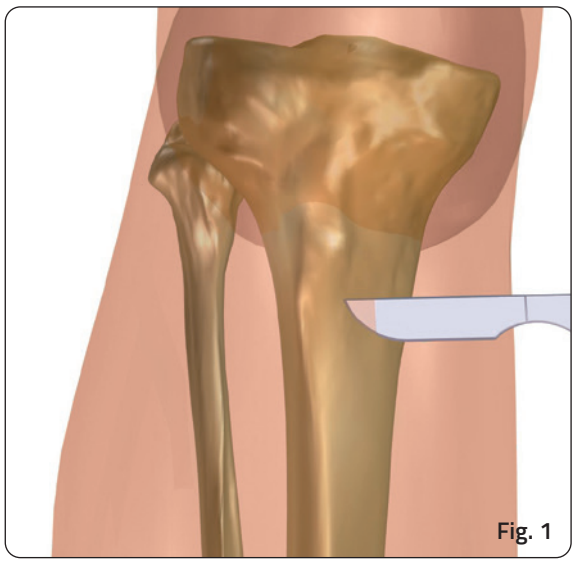


Fig. 1

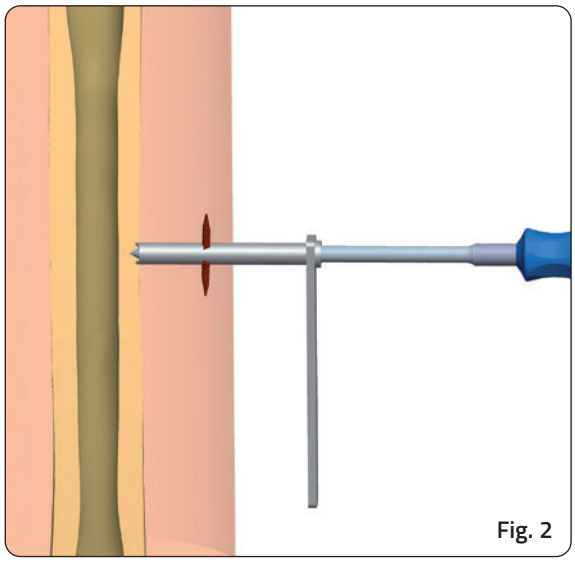


Fig. 2

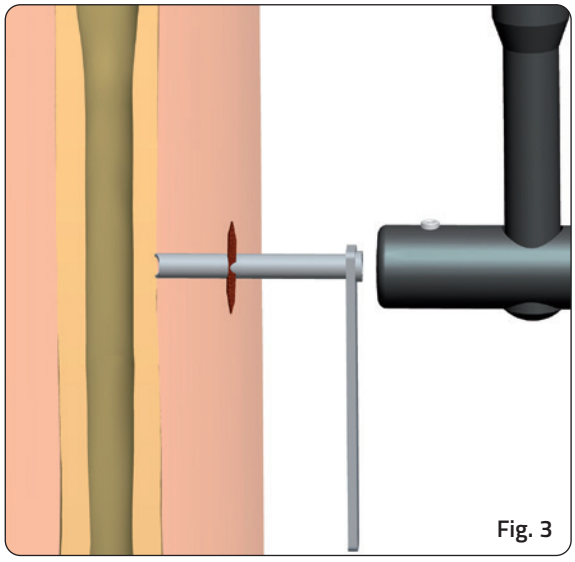


Fig. 3

4. Insert a screw through the screw guide into the bone using the Hand Drill **(Fig. 4a)**. While drilling, the Hand 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; four more turns are needed so that the tip just protrudes through the distal cortex. Diaphyseal bone screws should always be inserted across the diameter of the bone to avoid off axis placement. Off axis location of screws may result in screw threads lying entirely within the cortex and not traversing the medullary canal; this may weaken the bone. In all cases the surgeon should be mindful of the amount of torque required to insert the screw. In general, it is safer to drill a hole with a 4.8mm drill bit prior to insertion of these screws in diaphyseal bone **(Fig. 4b)**.

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

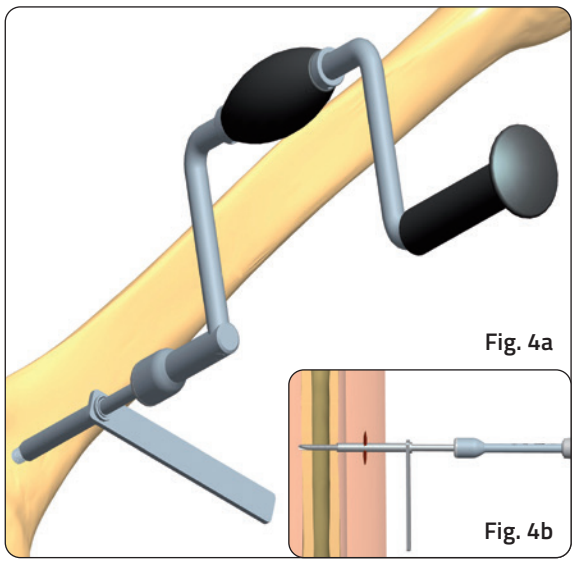
5. Insert the 4.8mm drill guide into the screw guide and introduce 4.8mm drill bit **(Fig. 5)**. Drill at 500-600 rpm through the first cortex, checking that the drill bit is at right angles to the bone. The force applied to the drill should be firm and the drilling time as short as possible to avoid thermal damage. Once the second cortex has been reached, reduce the drilling speed and continue through the bone. Ensure that the drill bit completely penetrates the second cortex.

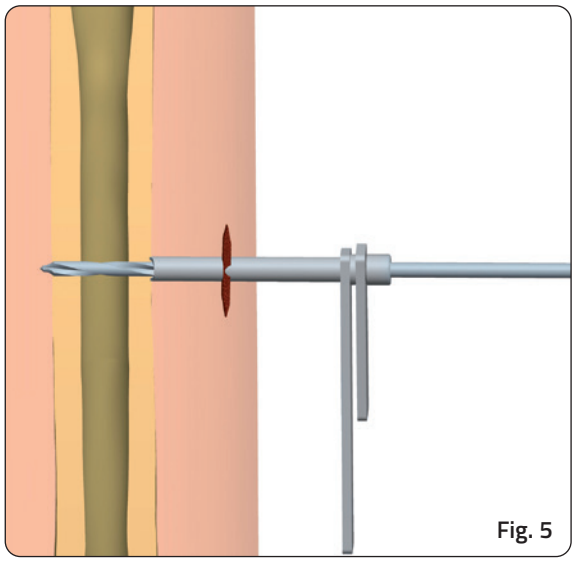
6. Remove the drill bit and drill guide, keeping pressure on the handle of the screw guide. The screw is inserted with the T-Wrench until it reaches the second cortex. A further 4-6 turns are required to ensure that about 2mm of the screw protrudes beyond the second cortex **(Fig. 6)**.

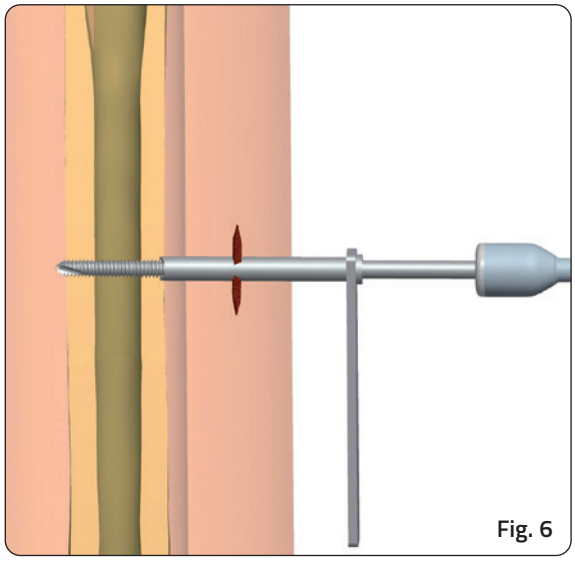
The XCaliber™ Self-Drilling Screws can be inserted by hand in cancellous bone. Pre-drilling is not often needed in this area. There is no need for the tip of the screw to protrude from the second cortex.

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage. Do not penetrate the entry cortex with the smooth shank to avoid damage to the bone.

PRECAUTION: Any attempt to back out a conical screw once it has been inserted may cause it to become loose.







XCaliber™ Bone Screw Design

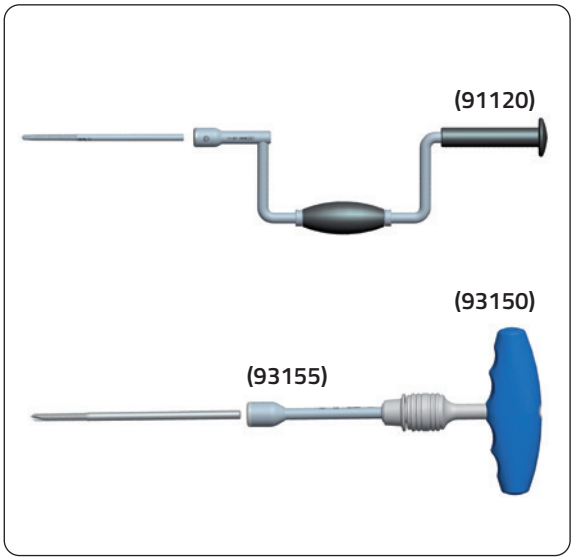
The threaded portion of the XCaliber Bone Screw tapers from 6.0mm to 5.6mm in diameter in order to provide an increasing radial preload during insertion. This maintains good fixation at the entry cortex, which is usually the first area subject to problems of loosening. Despite the tapered profile, some adjustment of bone screw penetration is possible owing to the inherent elasticity of bone. However, the screws should not be backed out for more than two full turns. The screws have a pointed tip and flute, which allow them to be inserted as self-drilling implants in cancellous bone without the need for pre-drilling. Direct insertion with a Hand Drill is advised in most situations, irrespective of whether uncoated or HA coated screws are used. However, when insertion of these self-drilling screws is performed in diaphyseal bone, pre-drilling is recommended; use a 4.8mm drill bit through a drill guide when the bone is hard. If the bone quality is poor or, as in the metaphyseal region, where the cortex is thin, a 3.2mm drill bit should be used.

PRECAUTION: Any attempt to back out a conical screw once it has been inserted may cause it to become loose.

XCaliber Bone Screws should never be inserted with a power tool. This may result in high temperatures and cell necrosis from too high insertion speeds. Screw insertion, whether or not pre-drilling has been performed, should always be with the XCaliber Hand Drill (91120) or Rachet T Handle + Screw Shaft Connection (93150 + 93155). The screws have a round shank that is gripped securely by the XCaliber T-handle or Hand Drill. It is important that moderate force is applied initially for the screw to engage and gain entry into the first cortex.

WARNING: Self-drilling conical screws with a thread diameter of 5mm or above should never be inserted with a power tool, but always by hand or with a Hand Drill.

7. Tibial screws are preferentially inserted in the sagittal (anteroposterior) plane. Insert the remaining screws using the same technique **(Fig. 7)**.



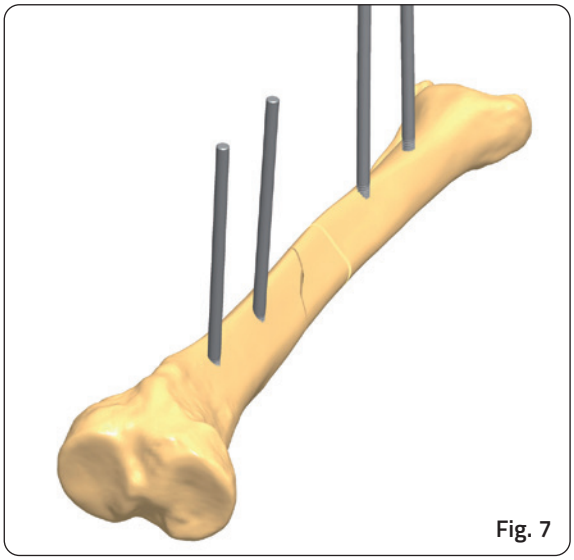


Fig. 7

Fixator Application

8. The two screws in each bone segment are joined by rods of suitable length; each one mounted with two clamps positioned about 30mm from the skin. They are then locked manually by turning the knurled metal ring clockwise **(Fig. 8)**.

9. A third rod is then used to join the first two rods together by 2 more clamps, which are not yet tightened. The surgeon now manipulates the fracture, if possible under X-ray control. When the position is satisfactory, the assistant locks all the clamps firmly by tightening the cams with the Universal T-Wrench or the 5mm Allen Wrench **(Fig. 9)**.

WARNING: The clamp must be closed first manually by turning the metal ring clockwise before locking it firmly by tightening the cam with the Universal T-Wrench or the 5mm Allen Wrench.

10. The screw shafts are then cut with the bone screw cutter **(Fig. 10)**. Although the screws can be cut before insertion, it is difficult to gauge the length accurately, and it is recommended that they are cut after the fixator has been applied. It is important that all of the screws are inserted first, and the fixator applied with the clamps locked firmly over the screws, about 30mm from the skin. The cutter can then be slid over the screw shanks in turn and the screws cut close to the fixator clamps. This will normally result in about 6mm of screw shank protruding from the clamp. The cutter is designed so that it can be used even when screws are in adjacent seats of the multi-screw clamp. 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.

PRECAUTION: When using screws, avoid cutting after screw insertion without the fixator applied. Cutting inserted screws without the fixator applied could transfer the cutting force to the bone.

PRECAUTION: To avoid causing injury: the ends of screws should be protected with special covers.

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

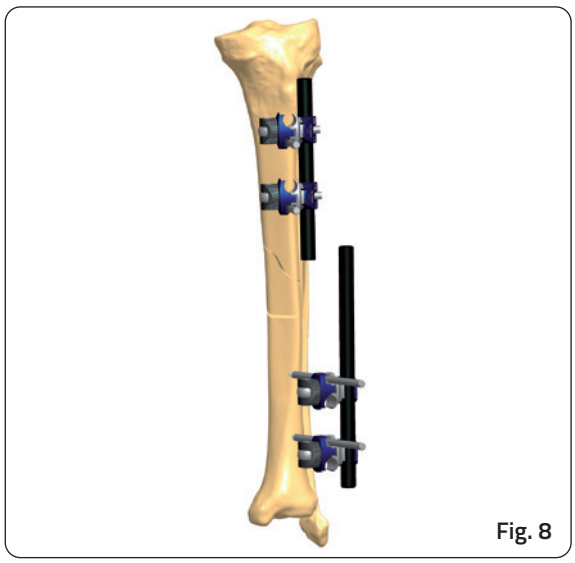


Fig. 8

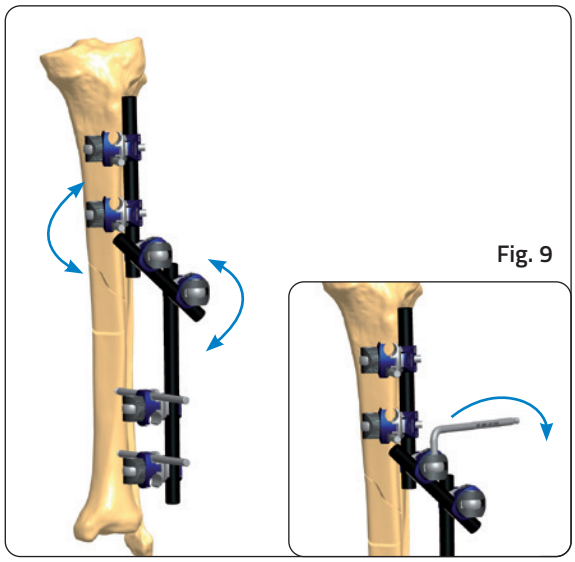


Fig. 9

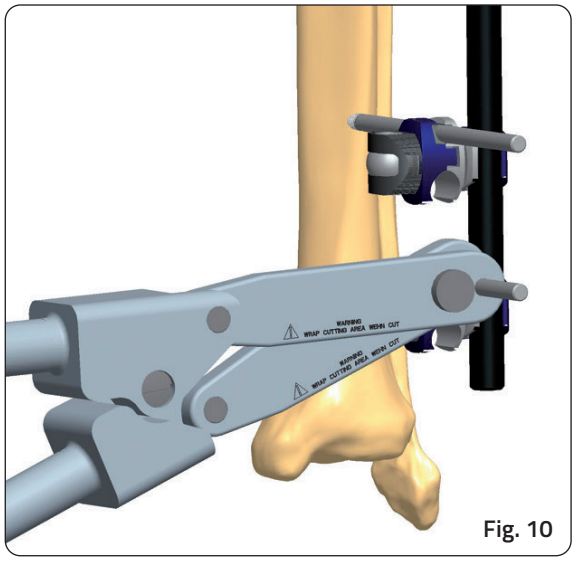


Fig. 10

MULTI-SCREW CLAMPS

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. 11)**.

Option 2

Use the Multi-Screw Clamp Guide 19940 as a template to insert screws perpendicular to the longitudinal axis of the bone **(Fig. 12)**.

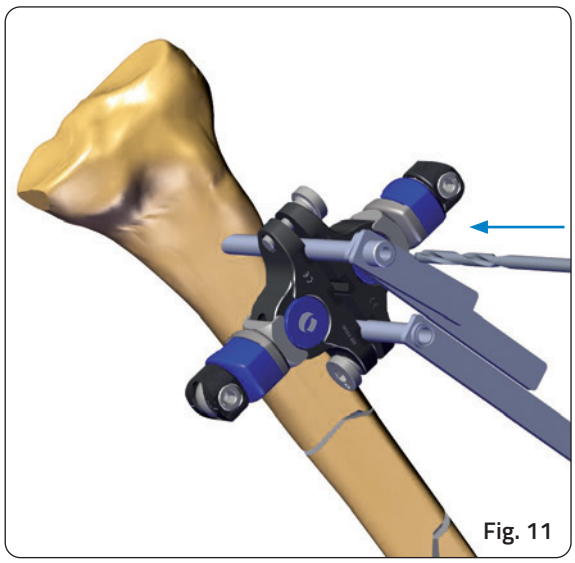


Fig. 11

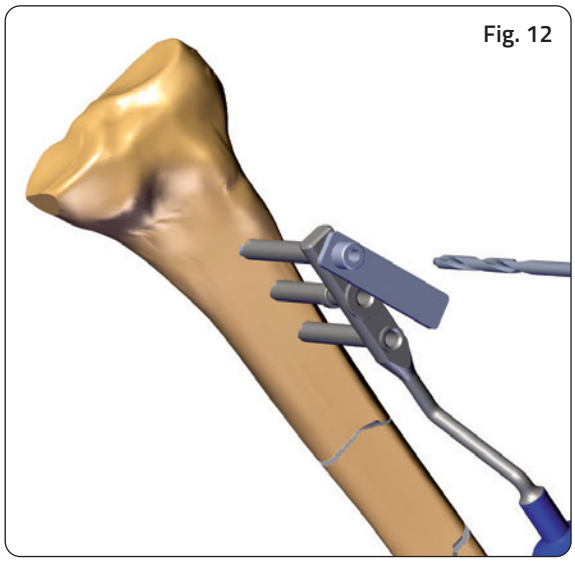


Fig. 12

APPLICATION BY ANATOMICAL SITE

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

The external fixator 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 antero-lateral. In damage control scenarios, the anterolateral plane is recommended. This facilitates:

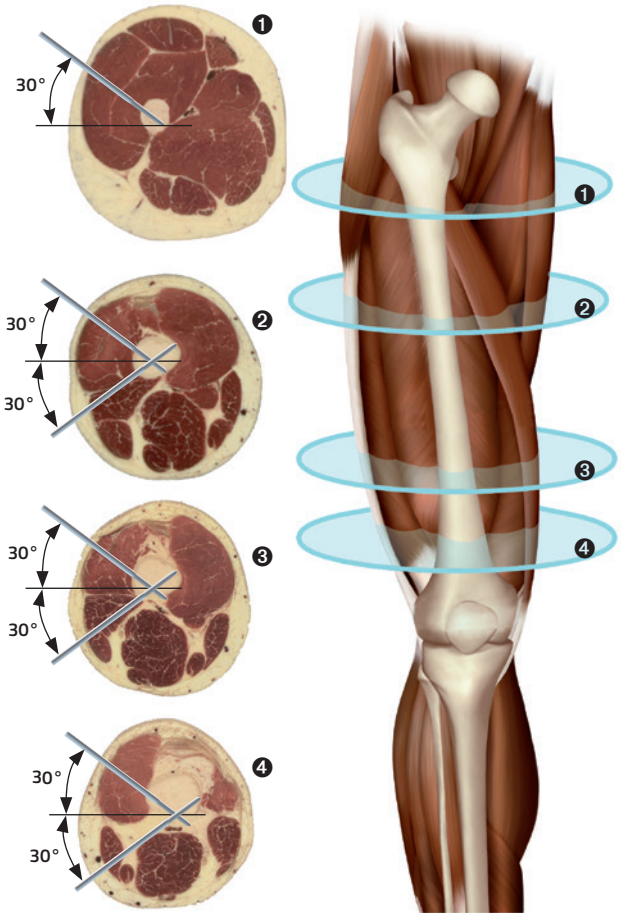
a. Easy connection to tibial assembly in order to span the knee securely.

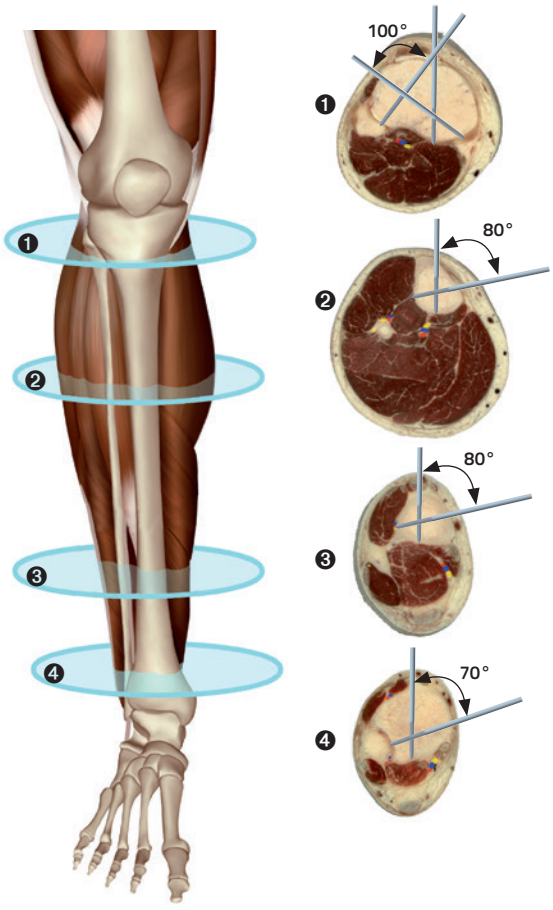
b. Sufficient clearance to enable lateral submuscular plating of the femur to be accomplished, should this be the desired conversion to definitive stabilisation.

Damage control configuration for distal periarticular fracture of the femur or tibia.
The femoral screws are anterolateral whereas the tibial ones 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.

KNEE AND TIBIA 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. If bi-planar stability is desired, the angles shown in the diagrams indicate the spread of screw position possible at each level. 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). If possible, screws should avoid the region just distal to the lower margin of the tibial tuberosity as this is the preferred location of the osteotomy for bone transport or lengthening should this be deemed necessary in the reconstruction of the tibia. Anteroposterior screws in the tibia facilitate lateral submuscular plating if this is the chosen definitive treatment.

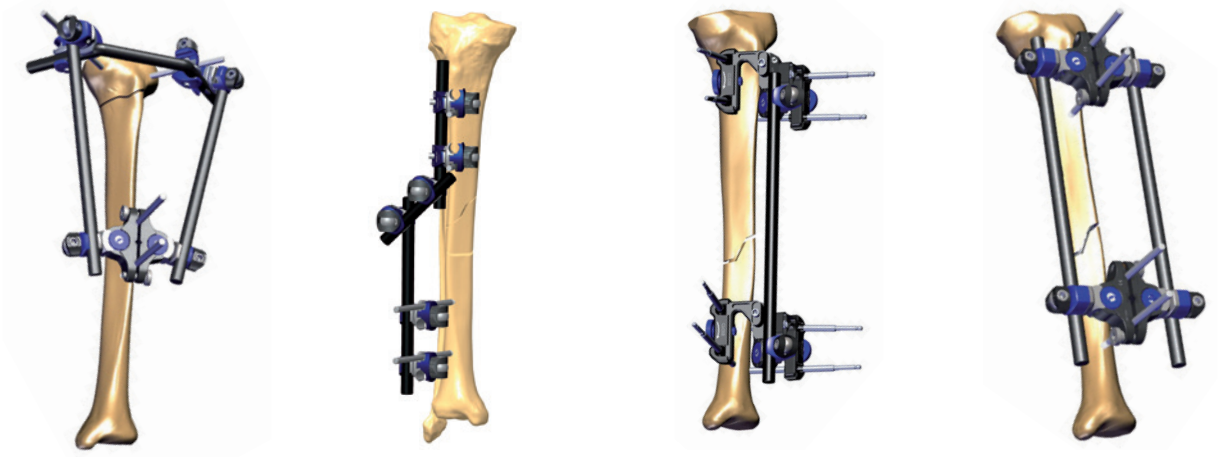




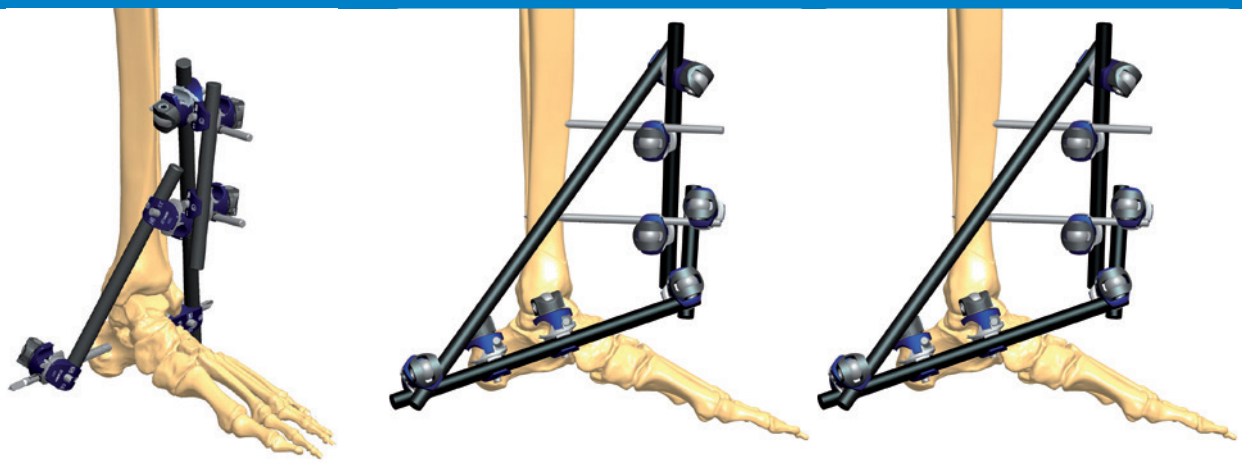
Femur

Knee

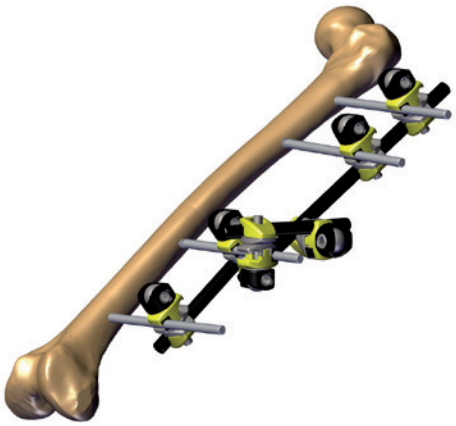
Tibia



Ankle



Paediatrics applications



PELVIS APPLICATION

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

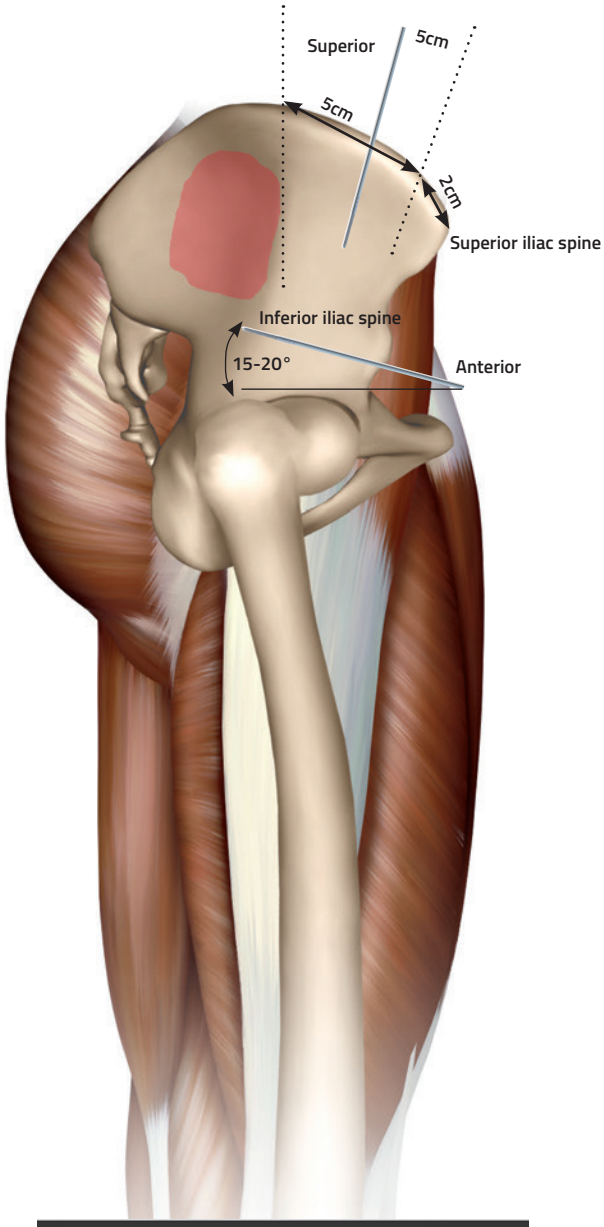
Supra-acetabular (Anterior) screw placement

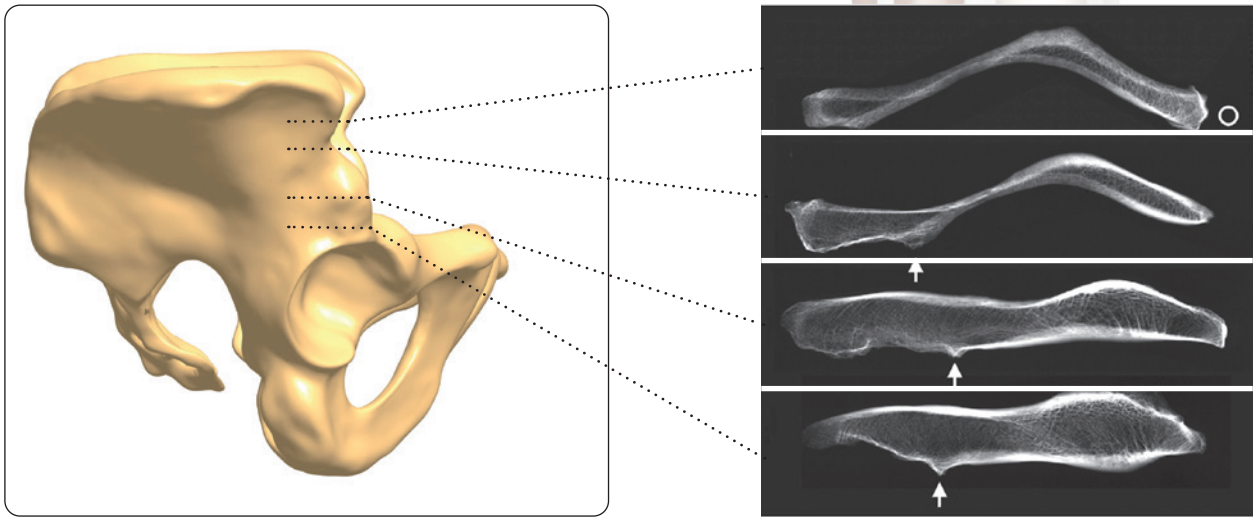
Given the wider cross sectional area and better bone purchase, the more technically difficult supra-acetabular screw placement is preferred over that of the iliac crest. Proceeding from the anterior superior iliac spine, the site of entry is approximately 4-6cm in a caudal direction. A skin incision 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 exposed and the screw guide placed firmly on the bone. The first 5-8mm of the self-drilling screw is tapped into the bone and then advanced gradually between the inner and outer cortical tables of the ilium, inclined about 15°-20° in a cranial direction and 30° internally with the patient supine on the table.

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 acetabolum and should follow the route between the outer and inner table of the ilium.

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

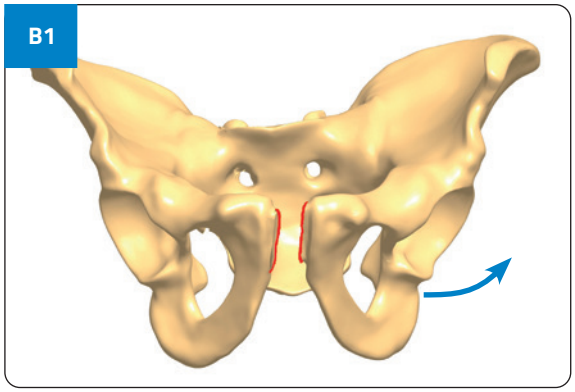


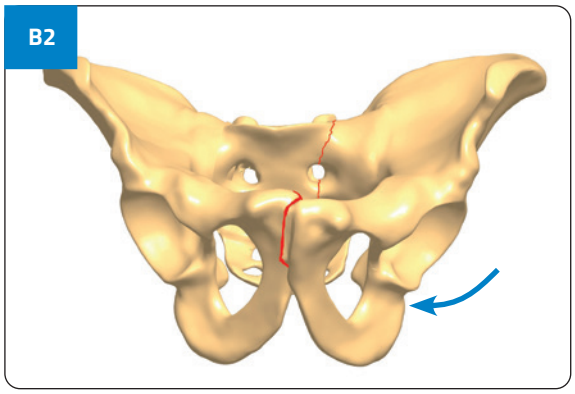


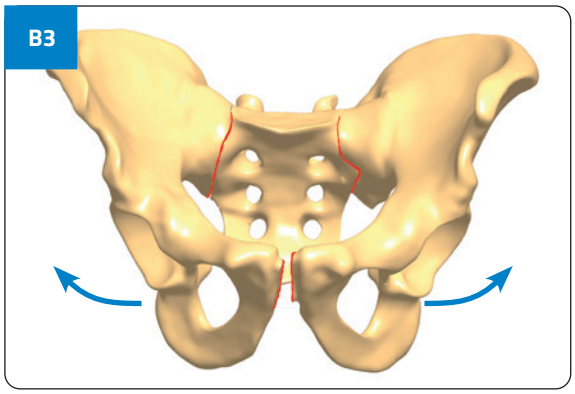
There are two main planes of instability: a horizontal plane and a vertical plane. Based upon this, pelvic ring instability may be divided into three types according to Tile's Classification, which indicate the type of management required. **Type A** injuries are stable and external fixation is therefore indicated only in **Type B** and **C** fractures to stabilise 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 stabilisation.

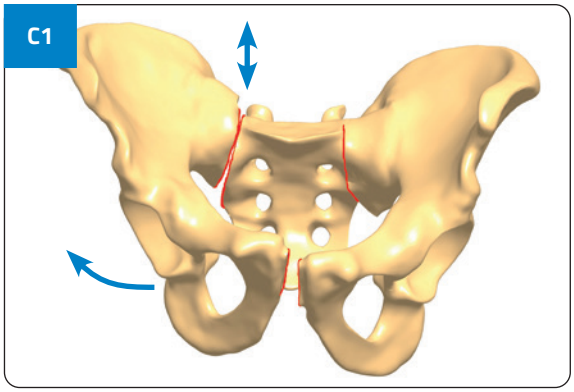
Type B - Rotationally unstable but vertically stable

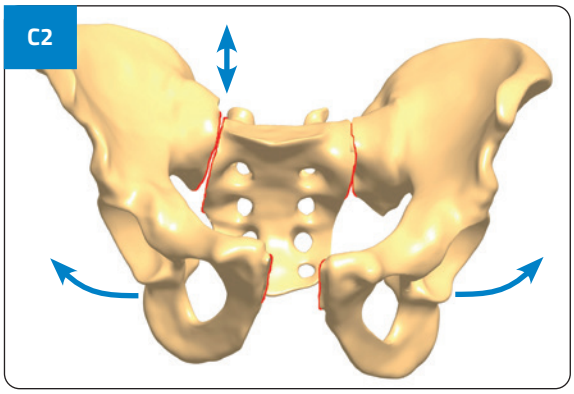


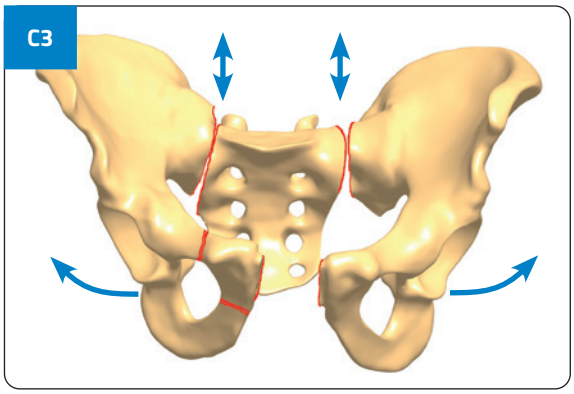




Type C - Rotationally and vertically unstable







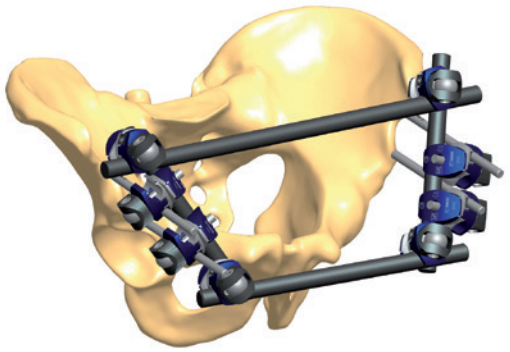
In **type B1** and **B3** injuries a diastasis of the symphysis greater than 2.5cm indicates a severe rotational instability and an increased pelvic volume. Therefore an external fixator is applied as an emergency procedure to reduce the pelvic volume and stop bleeding. However, the true instability 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.

PRECAUTION: Frame stability must be checked intra-operatively before the patient leaves the operating theatre.

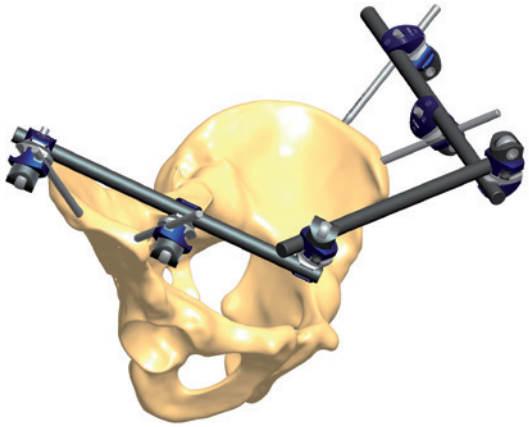
In **type B2** injuries external fixation is rarely necessary as an emergency procedure because the impaction of the fracture site leads to a sufficient stability and there is no increased pelvic volume. CT investigation may clarify the true fracture pattern and subsequently the correct treatment protocol, 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 in terms of weight bearing. Nevertheless, external fixation allows enough stability to reduce the pelvic volume and therefore the amount of bleeding. After resuscitation of the patient and further investigation, subsequent internal fixation of the posterior part of the pelvic ring may be considered.

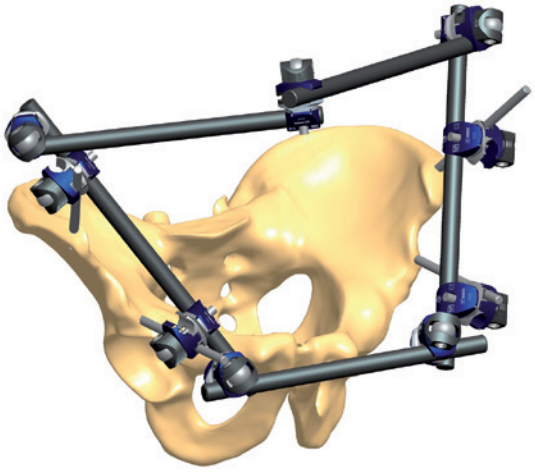
Anterior Application



Iliac Crest Application



Hybrid Application



OPERATIVE TECHNIQUE

1. Commence with the uninjured side. Make an incision just caudal 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 this 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-handle. Aim the screw 15-20 degrees cranial to avoid penetration of the hip joint and to enter the widest part of the ilium **(Fig. 1)**.

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

2. Insert two Kirschner Wires to establish the orientation of the hemipelvis: one from the iliac crest along the inner table of the ilium and one along the outer table **(Fig. 2)**. 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). In young patients (16 years and under), use a 3.2mm drill bit and drill guide to penetrate the hard cortex to a depth of 1cm. 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.

3. The two screws in each hemipelvis are joined by rods of suitable length, each one mounted with 2 clamps. They are then locked manually by turning the knurled metal ring clockwise. Two rods are then used to link the first two rods across the width of the pelvis (this can be at two levels as shown in **Fig. 3**) 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 the cams clockwise with the Universal T-Wrench or the 5mm Allen Wrench **(Fig. 3)**.

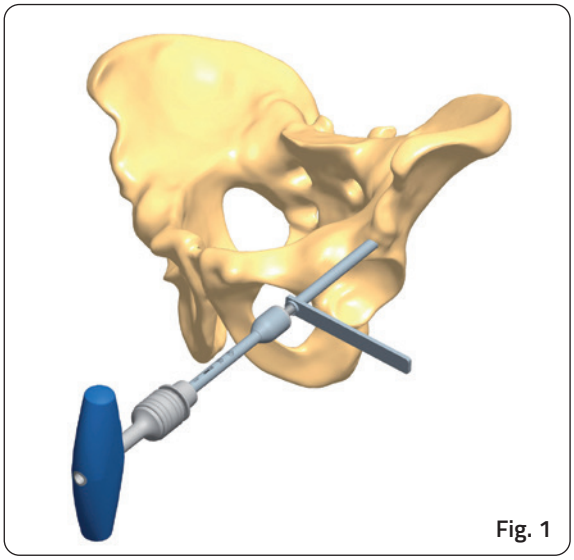


Fig. 1

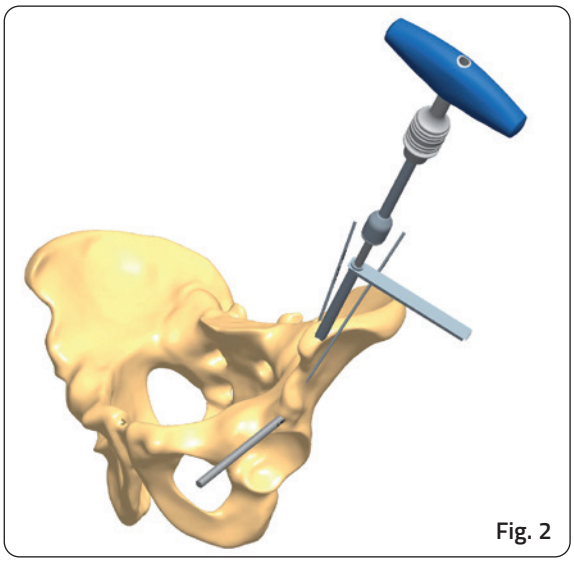


Fig. 2

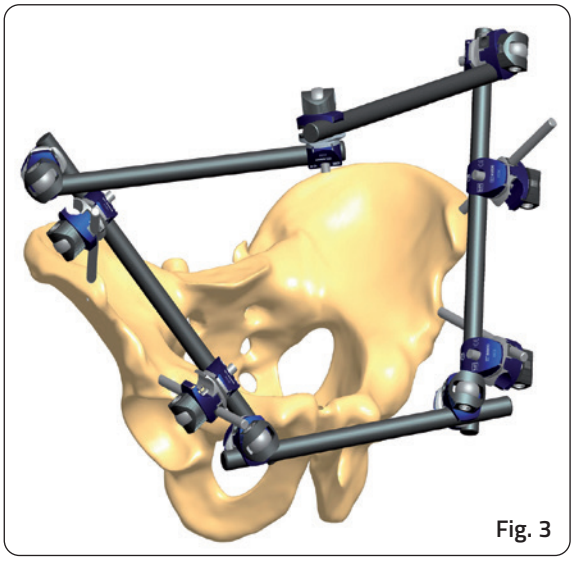
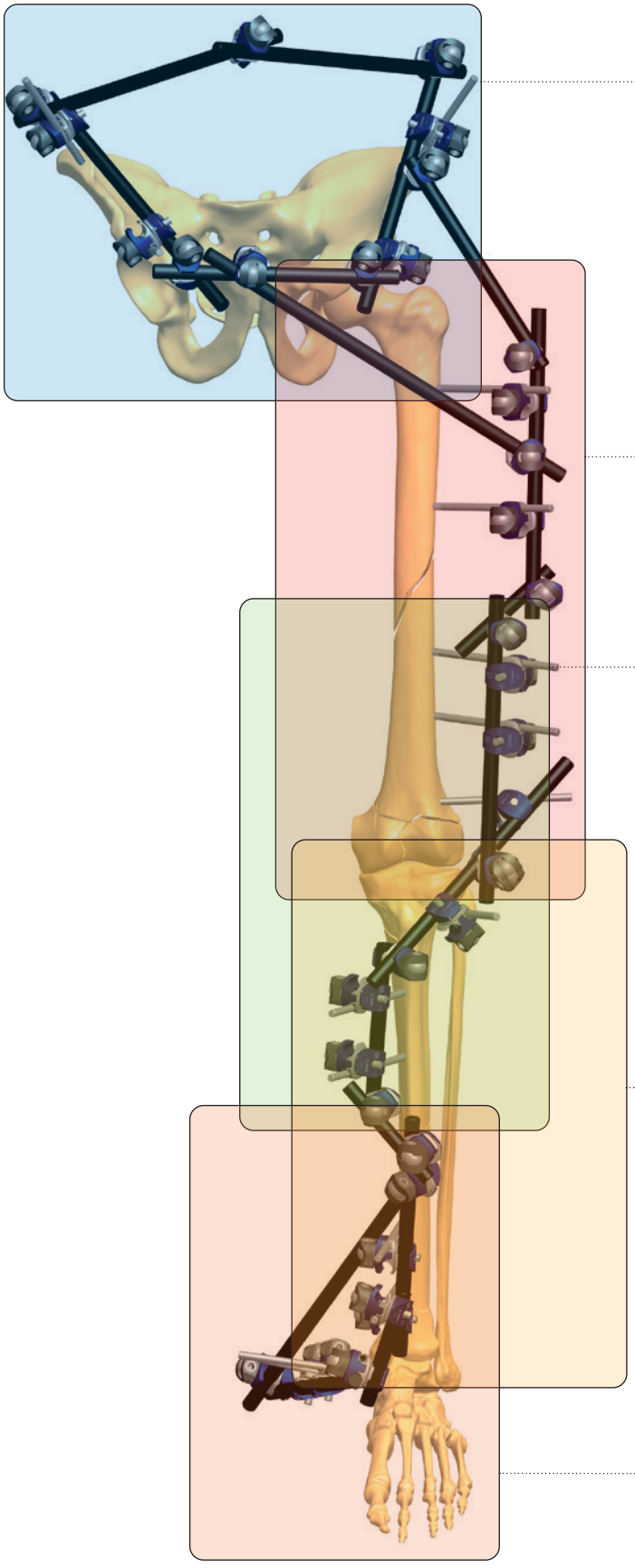


Fig. 3

DAMAGE CONTROL



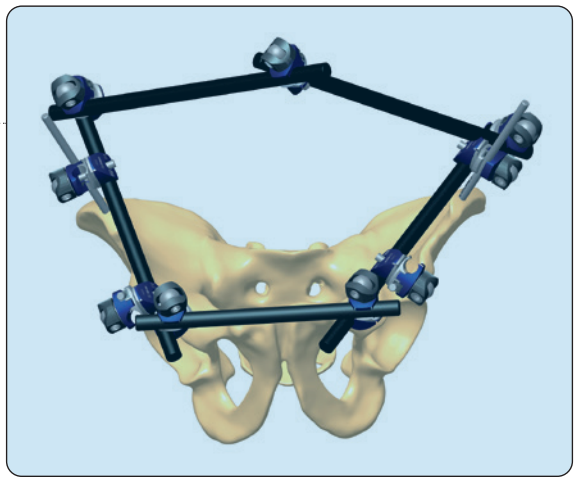
Pelvic application for unstable open book injuries

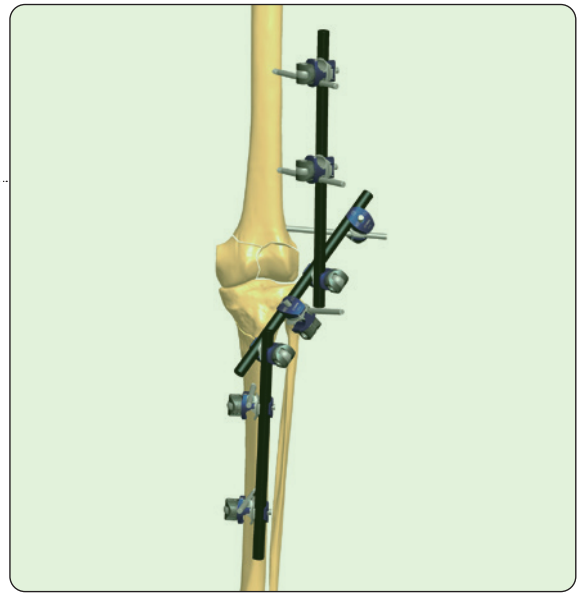
Femoral application for diaphyseal fractures

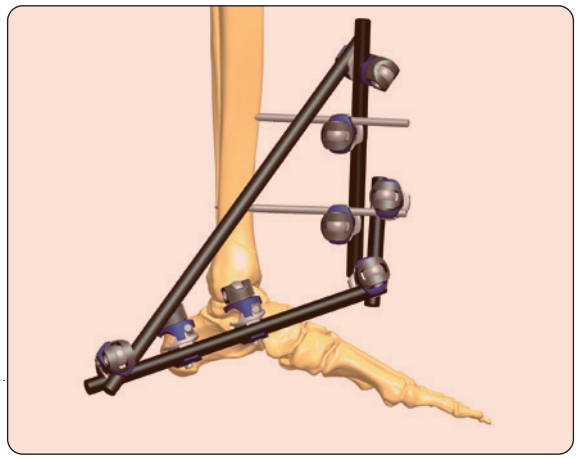
Knee spanning configuration for periartucular fractures
or ligamentous injuries of the knee

Tibial application for diaphyseal fractures

Ankle spanning configuration for periarticular fractures
or ligamentous injuries







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 halfpin. 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:

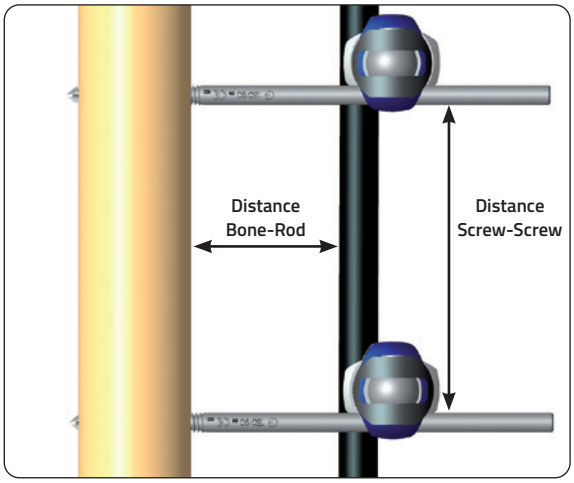
1. pin and rod clamps
2. connecting bars

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 diameters and lengths. The diameter of the bar used is important; stiffness increases with the fourth power of the radius.

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)**.

WARNING: The clamp must be closed first manually by turning the metal ring clockwise before locking it firmly by tightening the cam with the Universal T-Wrench or the 5mm Allen Wrench.



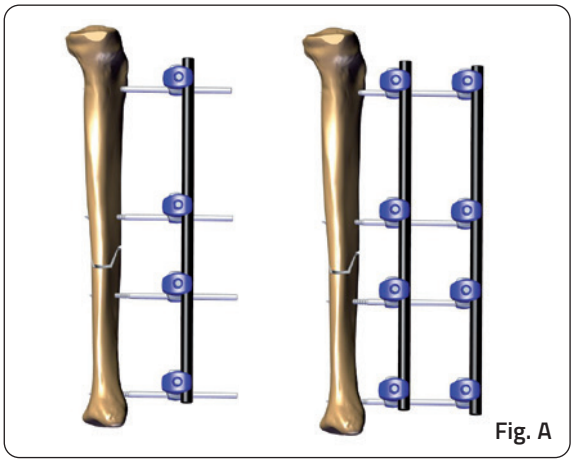


Fig. A

The fixator configuration

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 pin number from two to three in any one segment. The added benefit from increasing pin number from three to four is minimal, therefore three pins 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. 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 pin spread, the 'near and far' rule provides a guide; pins should be spread along a segment of bone such that the segment is spanned. The proximity of any pin to the fracture itself is cautioned as the pin may be within the fracture haematoma and thereby carry the risk of a pin site infection spreading to within the fracture. A rule of thumb of staying at least 2cm from the nearest fracture line helps **(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 and in general it should be kept as close as possible with enough room to facilitate pin site care; 40-50mm (roughly 2 finger breadths) from the bone surface if feasible **(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.

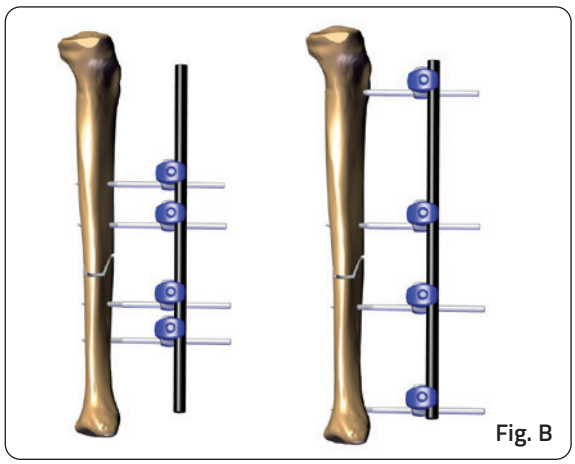


Fig. B

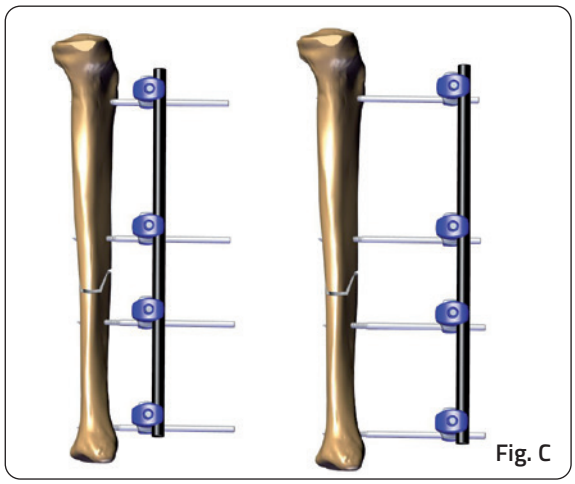
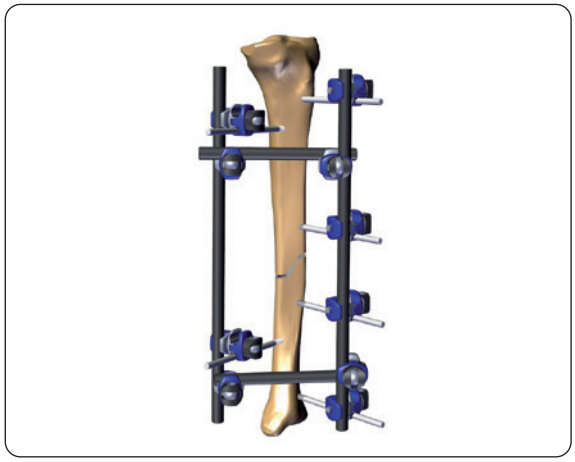


Fig. C



MRI INFORMATION

Non-clinical testing has demonstrated that the GALAXY FIXATION System 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".
Non-clinical testing, done according to ASTM F2052-06, F2213-06, F2182–11, F2119-07, demonstrated that a patient with the GALAXY FIXATION System can be safely scanned under the following conditions:

- Static magnetic field of 1.5Tesla and 3.0Tesla.
- Maximum spatial magnetic field gradient of 900-Gauss/cm (90mT/cm).
- Maximum whole-body-averaged Specific Absorption Rate (SAR) of 4.0W/kg in the First Level Controlled Mode for 15 minutes of scanning.
- No local transmit/receive coils must be used on the device.
- The GALAXY FIXATION System must be entirely outside the MR scanner bore. No part of the GALAXY FIXATION System may extend into the MR bore. Therefore MR scanning of body parts where the GALAXY FIXATION System is located is contraindicated.

Displacement Information

The GALAXY FIXATION System 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 Components. 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:

	1.5Tesla System	3.0Tesla System
Galaxy Fixation 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 System Components are placed outside the MR bore.

MR PATIENT SAFETY

MRI in patients with GALAXY FIXATION System can only be performed under these parameters. It is not allowed to scan the GALAXY FIXATION System directly. Using other parameters, MRI could result in serious injury to the patient. When the GALAXY FIXATION System 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 System 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 (part number preceded by 99-, e.g. 99-93030))*

* *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.*

RODS*

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

CLAMPS*

Part #	Description
93010	Large Clamp
93110	Medium Clamp
93310	Small Clamp
93020	Multi-screw Clamp

Part #	Description
93030	Large-Medium Transition Clamp
93120	Medium Multi-screw Clamp
99-93040	Large Double Multiscrew Clamp
99-93140	Medium Double Multiscrew Clamp

ELBOW HINGE*

Part #	Description
93410	Elbow Hinge

XCALIBER BONE SCREWS*

Part #	Shaft Ø	Thread Ø	Total L	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	Thread Ø	Total L	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

GALAXY TL-HEX CONNECTING POSTS

Part #	Description
93031	Galaxy TL-HEX Connecting Post L 50mm D 12mm
93032	Galaxy TL-HEX Connecting Post L 100mm D 12mm

XCALIBER CYLINDRICAL BONE SCREWS*

Part #	Shaft Ø	Thread Ø	Total L	Thread L
942630	6	6	260	30
942640	6	6	260	40
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
941630	6	6	180	30
941640	6	6	180	40
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
942540	6	5	260	40
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
943540	6	5	220	40
943550	6	5	220	50
943560	6	5	220	60
943570	6	5	220	70
941540	6	5	180	40
941550	6	5	180	50
941560	6	5	180	60
944530	6	5	150	30
944535	6	5	150	35
944540	6	5	150	40
944550	6	5	150	50
945530	6	5	120	30
945535	6	5	120	35
945540	6	5	120	40
946420	6	4	180	20
946430	6	4	180	30
946440	6	4	180	40
945420	6	4	150	20
945430	6	4	150	30
945440	6	4	150	40
944420	6	4	120	20
944430	6	4	120	30
944440	6	4	120	40
943420	6	4	100	20
943430	6	4	100	30
943440	6	4	100	40
948320	4	3	120	20
948325	4	3	120	25
948335	4	3	120	35
947320	4	3	100	20
947325	4	3	100	25
M310	3	3-2,5	50	18
M311	3	3-2,5	60	20
M312	3	3-2,5	60	25
M313	3	3-2,5	60	30
M321	3	3-2,5	70	15
M314	3	3-2,5	70	20
M315	3	3-2,5	70	25
M316	3	3-2,5	70	30
M317	3	3-2,5	100	30

The Orthofix Galaxy Fixation System Components not listed above have not been tested for heating, migration, or image artifact in the MR environment, and their safety is unknown. Scanning a patient carrying a frame that includes these components may result in patient injury.

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** *Special order only.*

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

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- Disk space: 50 Mbytes

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