

OPERATIVE TECHNIQUE

Prefix²

Fixator



Prefix²

Fixator

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Please kindly refer to the product IFU PQPFX, 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

The PreFix² Fixator is indicated for temporary external fixation. This may be needed when local facilities or the condition of the patient do not permit definitive fixation. Immediate stabilisation of long bone fractures in the lower limb is now an established part of the resuscitation process. High energy fractures with or without articular involvement frequently require emergency stabilisation to allow soft tissue recovery before definitive fixation. The PreFix² Fixator is designed to allow the surgeon to:

- Position screws where the condition of the bone and soft tissues permits;
- Reduce the fracture in order to restore alignment;
- Stabilise the fracture to allow the patient to be moved safely, either to a different location or to allow more urgent matters to be attended to.

Mechanical stability is assured by using an adequate number of Bone Screws and Rods. ¹⁾²⁾

The PreFix² Fixator can be applied to a single bone to stabilise a fracture, or across a joint if this is involved in the injury. This PreFix² Fixator consists of radiolucent rods of four lengths, independent screw clamps that allow the surgeon to insert the screws in any preferred position, rod connection clamps, and multiscrew clamps for parallel screw placement in T- or straight clamp configuration for later exchange with Orthofix LRS or External Fixators.

The Rods and Blue Multi Screw Clamps are strictly single patient use.

All PreFix² Clamps are MRI conditional.

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

2) Behrens F, Johnson W. *Unilateral External Fixation Methods to Increase and Reduce Frame Stiffness. Clin Orthop Relat Res* 1989;241:48-56.

MRI (MAGNETIC RESONANCE IMAGING) SAFETY INFORMATION

The components of the PREFIX, listed in Table 1, have been designed as MRI conditional up to 1.5 Tesla. The MRI components have been tested according to ASTM Standards F2052, F2182, F2213 and F2119.

The components of the PREFIX marked with "MR" are MRI conditional. PREFIX can only be guaranteed for MRI when using Orthofix XCALIBER™ Bone Screws and the following rods to build a frame:

Table 1. MRI conditional components of PREFIX

CLAMPS

Part #	Description
92012	Blue Rod Clip Clamp
92016	Blue Screw Clip Clamp
92026	Blue Transfixing Clip Clamp
92031	Blue Multi Screw Clamp

RODS

Part #	Description
92125	Rod 125mm long
92175	Rod 175mm long
92275	Rod 275mm long
92350	Rod 350mm long

XCALIBER SCREWS

Total Length (mm)	Thread Length (mm)						
	30	40	50	60	70	80	90
150	911530	911540	911550	911560	911570	911580	911590
260	912630	912640	912650	912660	912670	912680	912690

Please note that temperature changes reported below apply to the designated MRI system and characteristics used:

- MRI machine: PHILIPS Achieva 1.5T A-series
- Device Position: isocenter of MRI scanner
- Magnetic Field Strength: 1.5 Tesla
- Spatial gradient field: 9.37mT/m

If a different MRI system is used, temperature changes may vary. Contact is advised with the supplier of the MRI system and Orthofix.

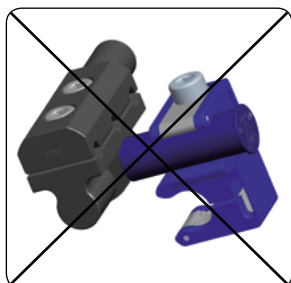
It has been shown by specific MRI tests that the MRI conditional components of PREFIX may be used for patients undergoing MRI procedures using up to 1.5 Tesla MR systems if certain specific conditions are followed. Three commonly used frames have been tested for MRI use at 1.5 Tesla. The results are as follows:

Blue Multi Screw Clamp

- A maximum temperature increase of 4.0°C has been measured at the tip of the indicated screws (Maximum Whole Body averaged SAR of 2W/kg for 6 minutes of scanning)



Part #	Description	Qty
92350	Rod 350mm long	2
911560	Self-Drilling XCaliber Screw, L 150mm, thread L 60mm	4
92012	Blue Rod Clip Clamp	4
92031	Blue Multi Screw Clamp	2



Z Configuration

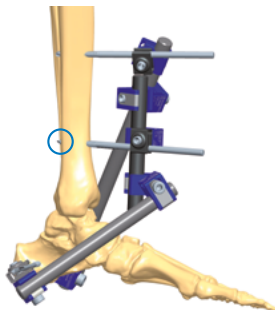
- A maximum temperature increase of 7.0°C has been measured at the tip of the most external screw (Maximum Whole Body averaged SAR of 2W/kg for 6 minutes of scanning)



Part #	Description	Qty
92125	Rod 125mm long	2
92275	Rod 275mm long	1
911560	Self-Drilling XCaliber Screw, L 150mm, thread L 60mm	2
911540	Self-Drilling XCaliber Screw, L 150mm, thread L 40mm	2
92016	Blue Screw Clip Clamp	4
92012	Blue Rod Clip Clamp	2

Ankle Configuration

- A maximum temperature increase of 2.1°C has been measured at the tip of the indicated screw (Maximum Whole Body averaged SAR of 2W/kg for 6 minutes of scanning)
- At the indicated clamp a temperature increase of 12.2°C (with reference to room temperature) has been measured



Part #	Description	Qty
92125	Rod 125mm long	1
92175	Rod 175mm long	1
92275	Rod 275mm long	1
911540	Self-Drilling XCaliber Screw, L 150mm, thread L 40mm	2
92080	Transfixing Pin, thread L 80mm, thread Ø 5mm, shaft Ø 4mm	1
92016	Blue Screw Clip Clamp	2
92012	Blue Rod Clip Clamp	2
92026	Blue Transfixing Pin Clamp	2

These tests have been performed in areas where the greatest temperature increase is expected with commonly used frames: at the tip and surrounding the tip of the most external screw. Due to the versatility of the system, an unlimited number of frames can be built, which makes it impossible to test every construct. There are factors that can influence these results (e.g. the number of screws used). Therefore, it is recommended that each frame be evaluated by a radiologist or MR scientist before the MRI procedure is undertaken to ensure patient safety. Since different frame configurations and frame sizes might lead to higher temperature increases, Orthofix recommends that the SAR settings are minimized as much as possible. None of the components should move or migrate in the 1.5 Tesla MRI environment. Non-clinical testing has not been performed to rule out the possibility of component movement or migration at static magnetic field strengths higher than 1.5 Tesla or maximum spatial gradients higher than 9.37mT/m.

IMAGE ARTIFACTS

MR image quality may be compromised if the area of interest is in the same vicinity or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. Representative components used to assemble MRI Conditional PREFIX have been evaluated in MRI chamber. Typical values of artifact sizes are reported below.

Part #	Description	Qty
92275	Rod 275mm long	1
92012	Blue Rod Clip Clamp	1
92016	Blue Screw Clip Clamp	1
911560	Self-Drilling XCaliber Screw, L 150mm, thread L 60mm	1

Pulse Sequence	Spin-echo	Gradient-echo
TR (ms)	500	334
TE (ms)	4,8	4,6
Slice Thickness (mm)	5	5
Matrix size	230x288	230x288
Flip Angle	90°	30°
Imaging Plane	perpendicular to static field	perpendicular to static field
Artifact Size (mm)	16	34

Part #	Description	Qty
92350	Rod 350mm long	1
92012	Blue Rod Clip Clamp	1
92031	Blue Multi Screw Clamp	1
911560	Self-Drilling XCaliber Screw, L 150mm, thread L 60mm	2

Pulse Sequence	Spin-echo	Gradient-echo
TR (ms)	500	334
TE (ms)	4,8	4,6
Slice Thickness (mm)	5	5
Matrix size	230x288	230x289
Flip Angle	90°	30°
Imaging Plane	perpendicular to static field	perpendicular to static field
Artifact Size (mm)	20	46

The components of the PREFIX not marked with "MR" have not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. They have not been tested for heating, migration, or image artifact in the MR environment. Their safety in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

FEATURES AND BENEFITS

Rods

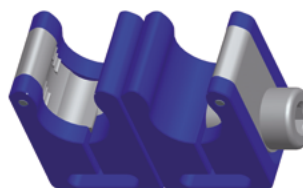
- The largest diameter (14mm) rod available for temporary external fixation
- Strong radiolucent rod in four different lengths

Part #	Description
92125	Rod 125mm long
92175	Rod 175mm long
92275	Rod 275mm long
92350	Rod 350mm long



92012 Blue Rod Clip Clamp

- Quick, stable connection of two rods in all planes
- Excellent bar torsional stability



92012

92016 Blue Screw Clip Clamp

- Free screw placement for rapid assembly of desired frame construction
- Easy, fast connection of 6mm screws



92016

92026 Blue Transfixing Pin Clamp

- For use in ankle-spanning configurations
- Easy, fast connection of 4mm transfixing pins

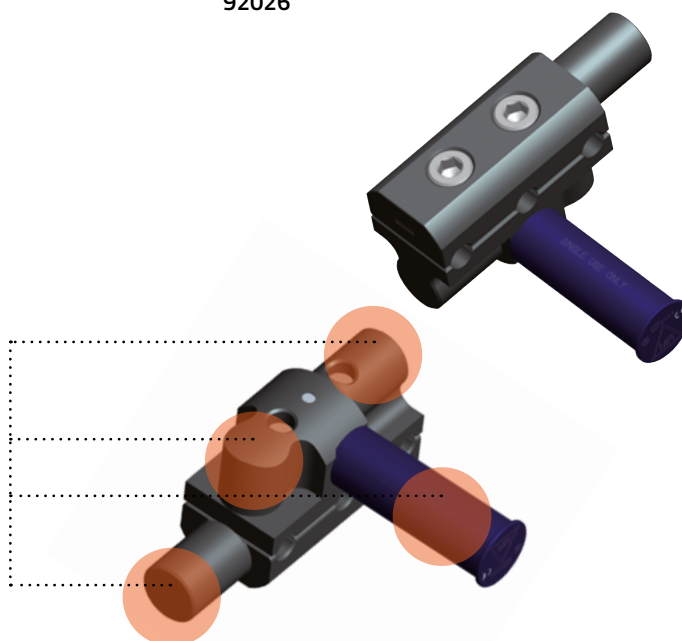


92026

92031 Blue Multi Screw Clamp

- Parallel screw positioning in T- or straight clamp configuration for later exchange with Orthofix External Fixators
- When using the Multi-Screw Clamp, two rods must always be used to increase frame stiffness.
- Single use

- Four possible connections for best placement of rod clip clamp



EQUIPMENT REQUIRED

Cross Knee Application



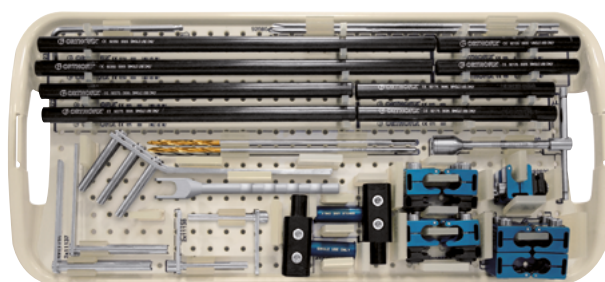
Cross Ankle Application



92995 PreFix² STERILIZATION BOX, EMPTY

can accommodate:

Part #	Description	Qty
1100201	DRILL BIT Ø 4.8MM L 240MM	2
11137	SCREW GUIDE, L 80MM	2
11138	DRILL GUIDE Ø 4.8MM L 60MM	2
19930	MULTI SCREW CLAMP GUIDE	2
30017	ALLEN WRENCH 5MM	1
91150	UNIVERSAL T-WRENCH	1
92012	BLUE ROD CLIP CLAMP	4
92016	BLUE SCREW CLIP CLAMP	8
92017	PREFIX II CLAMP HOLDER	1
92026	BLUE TRANSFIXING PIN CLAMP	2
92031	BLUE MULTI SCREWS CLAMP	2
92050	TRANSFIXING PIN, THREAD L 50MM SHAFT D 4MM, THREAD D 5MM	1
92080	TRANSFIXING PIN, THREAD L 80MM SHAFT D 4MM, THREAD D 5MM	1
92125	ROD 125MM LONG	2
92175	ROD 175MM LONG	2
92275	ROD 275MM LONG	2
92350	ROD 350MM LONG	2



EQUIPMENT FOR SCREW APPLICATION

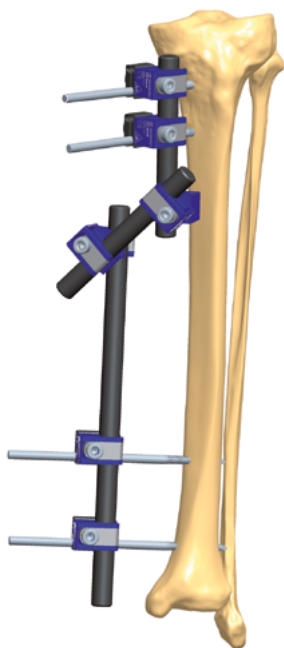
(not included in the box)

Part #	Description	Qty
11111	HAMMER	1
91120	MANUAL DRILL	1
91101	BONE SCREW CUTTER	1

For Cleaning, Disinfection, Sterilisation and Maintenance of Instrumentation please refer to PQPFX.

Diaphyseal Applications and Kits

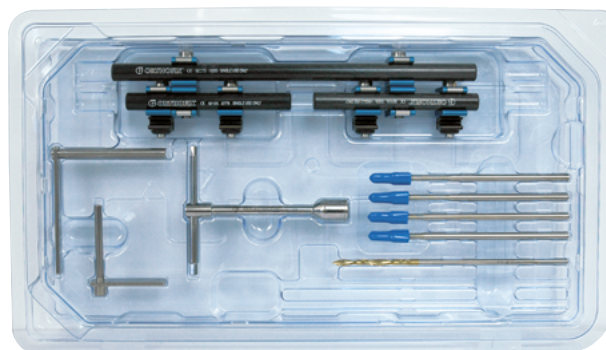
Tibia



99-92501 PreFix² Diaphyseal Complete Kit Sterile Short Screws

consisting of:

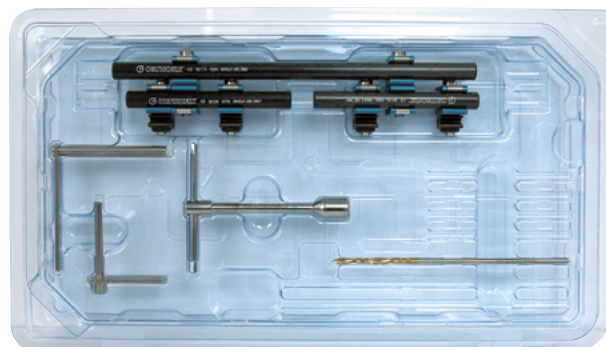
Part #	Description	Qty
92125	Rod 125mm long	2
92275	Rod 275mm long	1
92012	Blue Rod Clip Clamp	2
92016	Blue Screw Clip Clamp	4
11137	Screw Guide, 80mm	1
11138	Drill Bit Guide, Ø 4.8mm, L 60mm	1
1100101	Drill Bit 4.8mm	1
91150	Universal T-Wrench	1
911560	Self-Drilling XCaliber Screw, L 150mm, thread L 60mm	2
911540	Self-Drilling XCaliber Screw, L 150mm, thread L 40mm	2



99-92502 PreFix² Diaphyseal Complete Kit Sterile No Screws

consisting of:

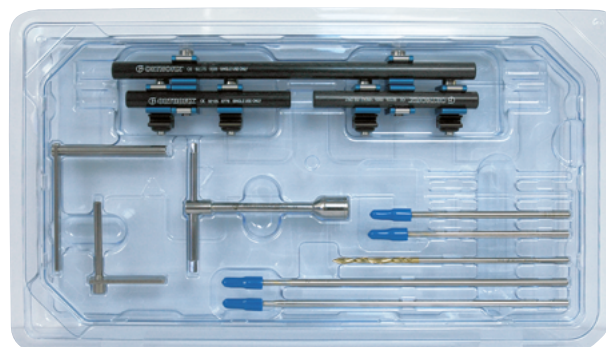
Part #	Description	Qty
92125	Rod 125mm long	2
92275	Rod 275mm long	1
92012	Blue Rod Clip Clamp	2
92016	Blue Screw Clip Clamp	4
11137	Screw Guide, 80mm	1
11138	Drill Bit Guide, Ø 4.8mm, L 60mm	1
1100101	Drill Bit 4.8mm	1
91150	Universal T-Wrench	1



99-92503 PreFix² Diaphyseal Complete Kit Sterile Long Screws

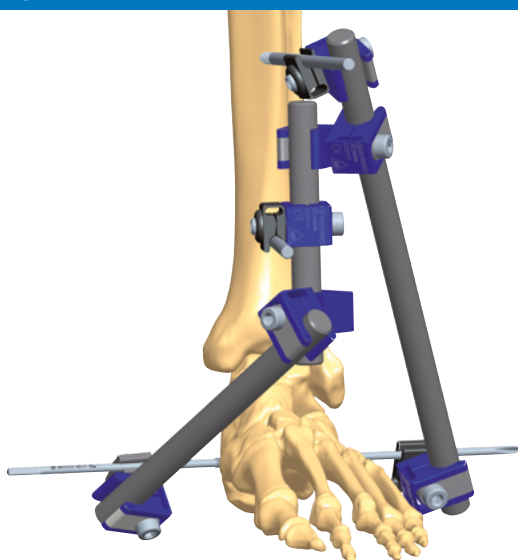
consisting of:

Part #	Description	Qty
92125	Rod 125mm long	2
92275	Rod 275mm long	1
92012	Blue Rod Clip Clamp	2
92016	Blue Screw Clip Clamp	4
11137	Screw Guide, 80mm	1
11138	Drill Bit Guide, Ø 4.8mm, L 60mm	1
1100101	Drill Bit 4.8mm	1
91150	Universal T-Wrench	1
911550	Self-Drilling XCaliber Screw, L 150mm, thread L 50mm	2
912650	Self-Drilling XCaliber Screw, L 260mm, thread L 50mm	2



Ankle Application and Kit

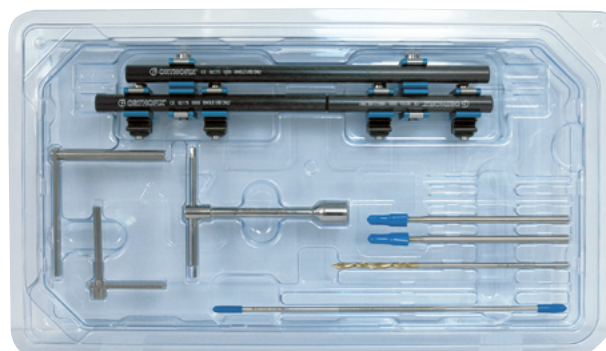
Ankle



99-92504 PreFix² Ankle Complete Kit Sterile

consisting of:

Part #	Description	Qty
92125	Rod 125mm long	1
92275	Rod 275mm long	1
92175	Rod 175mm long	1
92012	Blue Rod Clip Clamp	2
92016	Blue Screw Clip Clamp	2
92026	Blue Transfixing Pin Clamp	2
11137	Screw Guide, 80mm	1
11138	Drill Bit Guide, Ø 4.8mm, L 60mm	1
1100101	Drill Bit 4.8mm	1
91150	Universal T-Wrench	1
911540	Self-Drilling XCaliber Screw, L 150mm, thread L 40mm	2
92080	Transfixing Pin, thread L 80mm, thread Ø 5mm, shaft Ø 4mm	1



SURGICAL APPROACHES

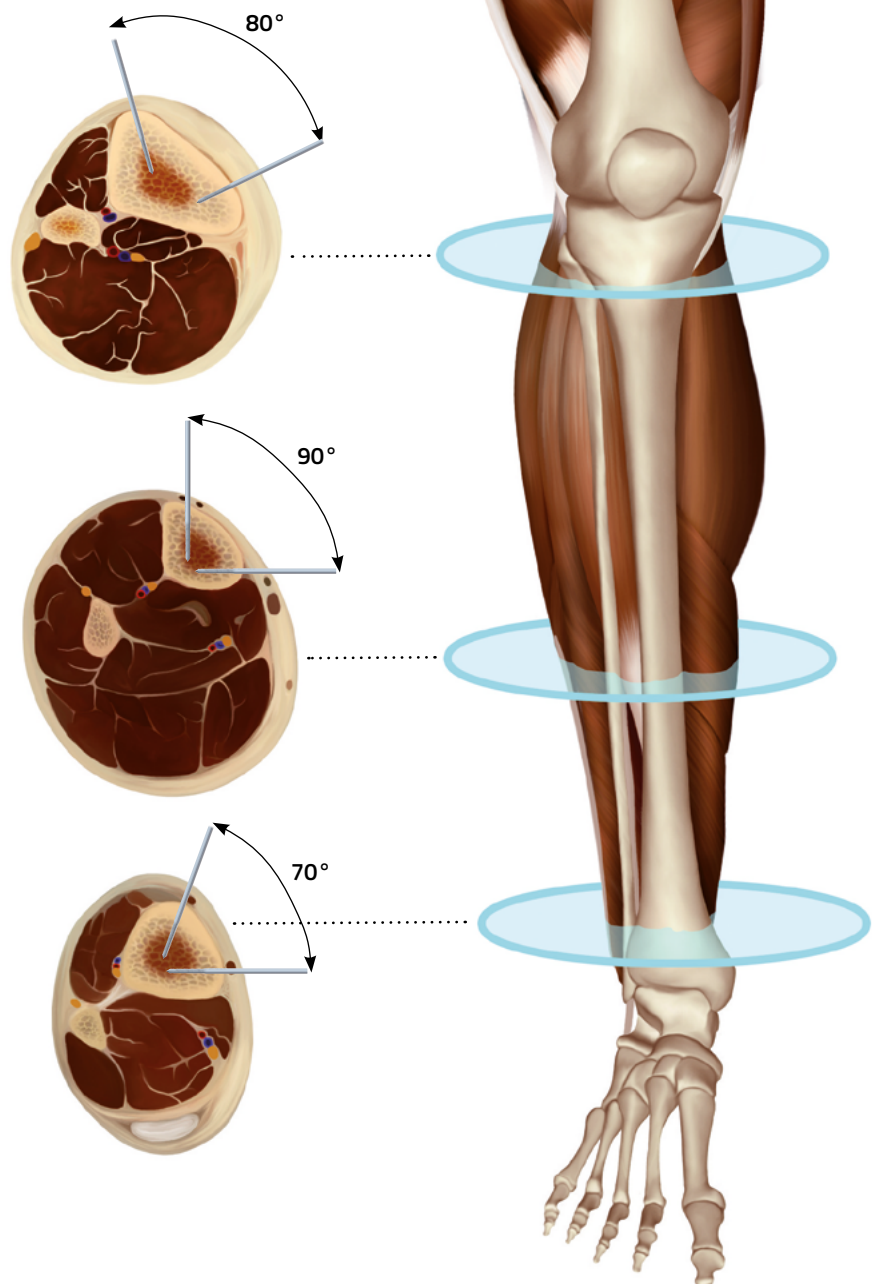


PRECAUTION: Screws and wires must be inserted with full knowledge of the safe corridors to avoid damage to the anatomical structures.

Approach to the tibia

Screw insertion in the tibia is within the safe corridors illustrated in the cross-sections. If bi-planar stability is desired, the angles shown in the diagrams indicate the spread of screw position possible at each level. Damage to the anterior tibial artery is prevented if the lateral surface of the distal tibia is avoided. Similarly, tendon transfixation is prevented if screws are not placed across the anterolateral surface at this level. For this reason, placement in the tibia antero-medial application is advisable.

In anticipation of secondary intervention for definitive internal fixation, it is important to position these screws away from possible surgical access routes.



TIBIA APPLICATION

Screw Insertion

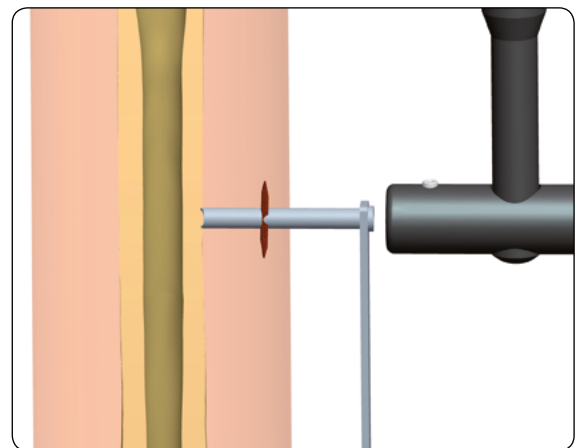
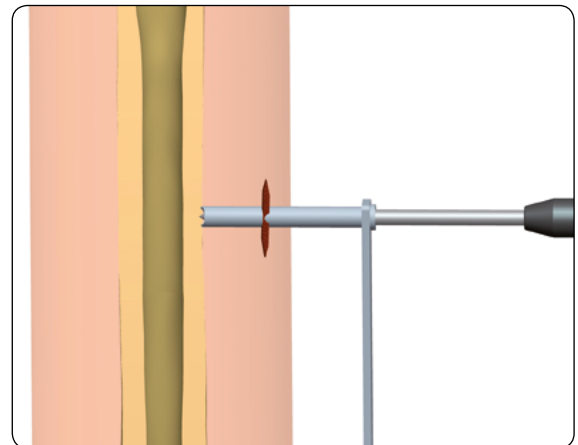
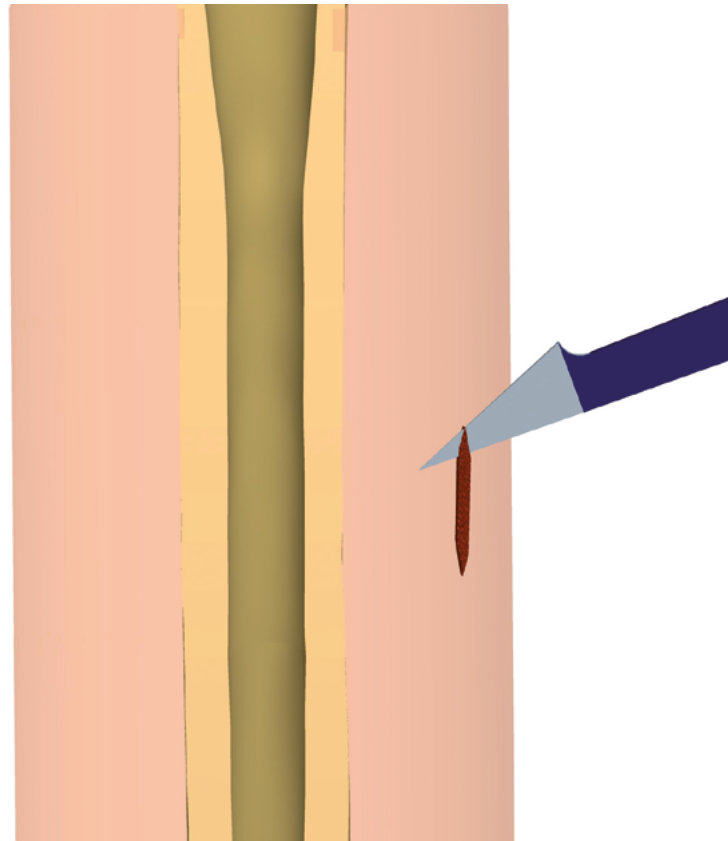
Screw positions should be planned with regard to existing injuries and possible future plastic surgery or internal fixation procedures. X-rays of the fracture in two planes should be available. In general, screws should be placed antero-medially in the tibia if possible. Screws should be positioned for maximum mechanical stability in each bone segment, as far apart as the positions of the fracture and neighboring joints allow.

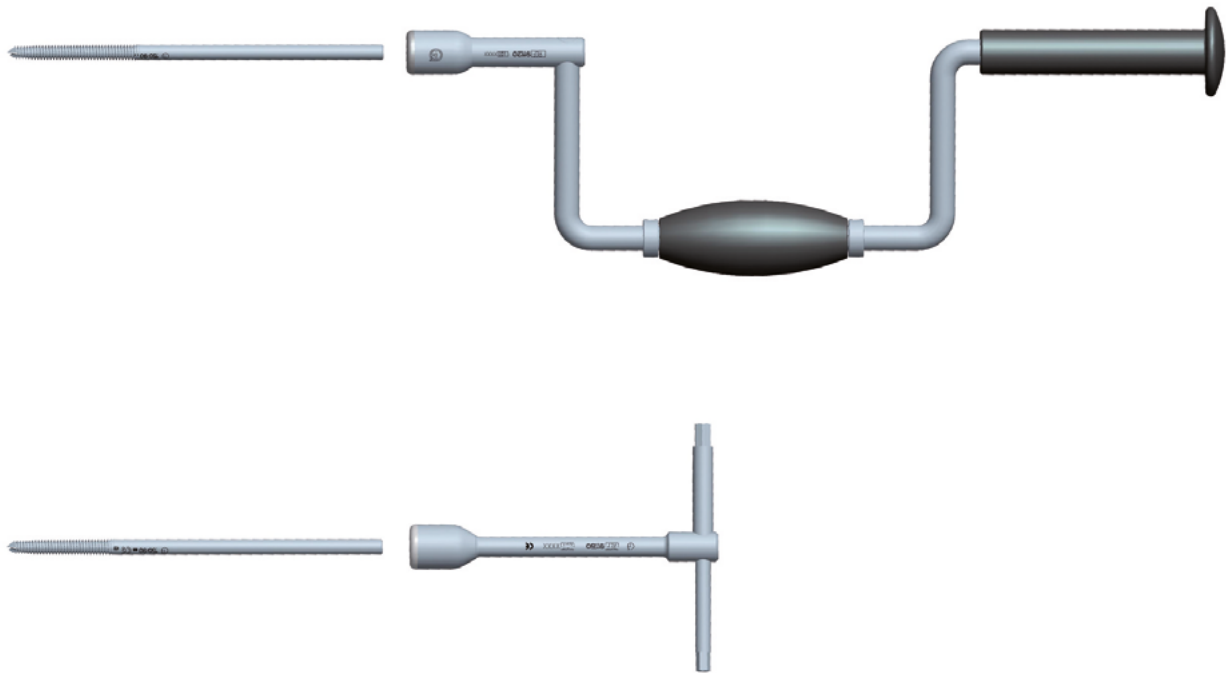
Insert two screws into each main fragment free-hand using the following technique: make a 15mm incision through skin and deep fascia. Use blunt dissection to reach the underlying bone.

Insert a screw guide perpendicular to the longitudinal axis of the bone. Use a trocar to locate the midline by palpation. Keeping the screw guide in contact with the cortex by gentle pressure, withdraw the trocar, and tap the screw guide lightly to anchor its distal end.

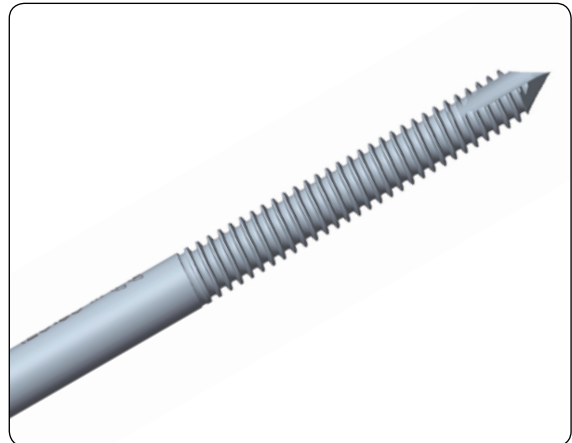


PRECAUTION: Diaphyseal Bone Screws should always be inserted perpendicular to and in the center of the bone axis to avoid weakening it.





The XCaliber Bone Screw Thread tapers from 6.0mm to 5.6mm in diameter in order to provide an increasing radial preload during insertion. This maintains good fixation of the entry cortex. 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 all have a pointed tip and flute, which allow them to be inserted self-drilling 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 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. When the bone quality is poor, or 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 too high an insertion speed being used, which causes high temperatures and cell necrosis. Screw insertion, whether or not pre-drilling has been performed, should always be with the XCaliber Hand Drill or T-Wrench only. It is important that moderate force is applied for the screw to gain entry into the first cortex. The screws have a round shank. They are inserted with the XCaliber T-Wrench or Hand Drill, which pushes over and grips the shank securely.



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.

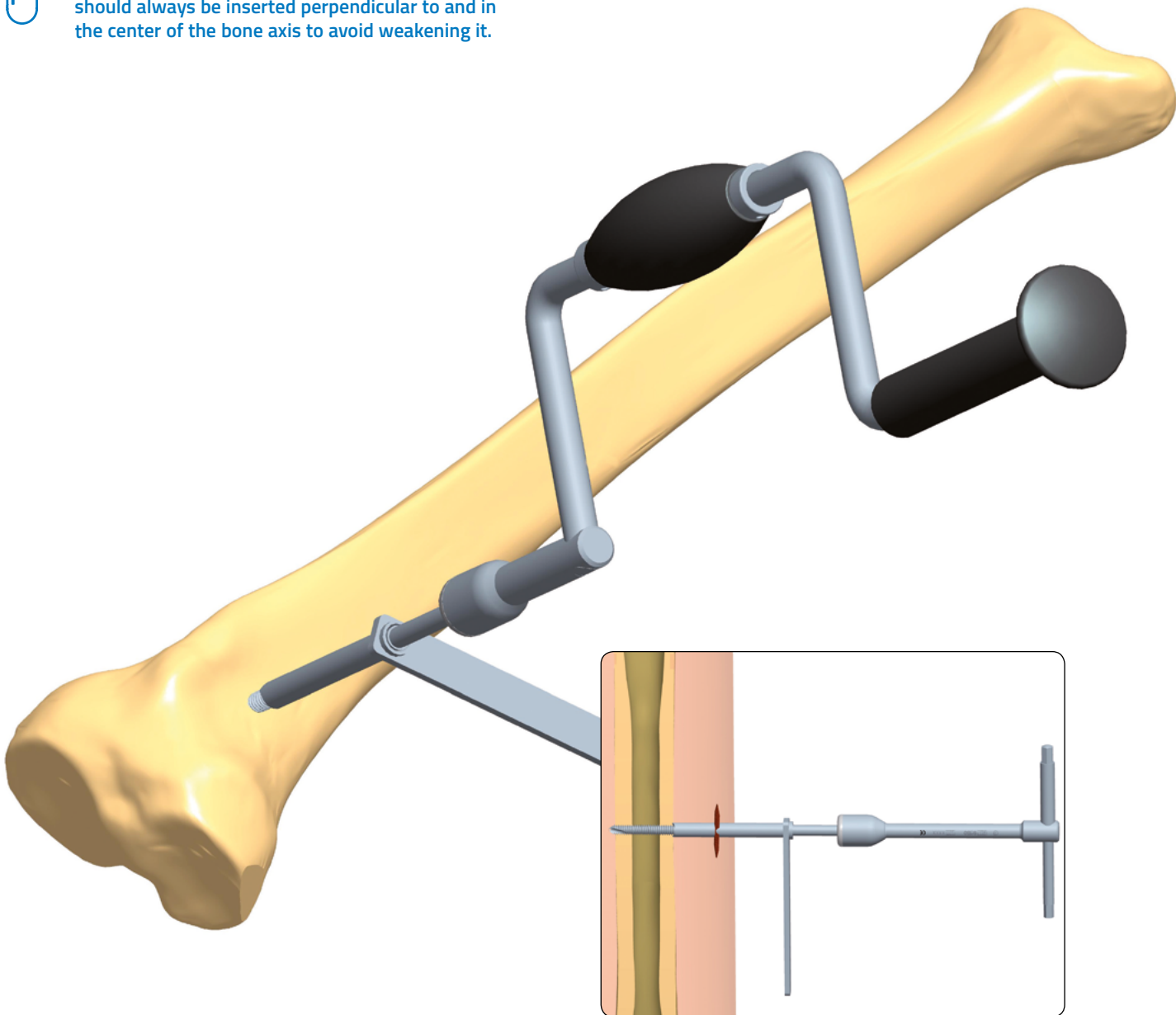
Insert a screw through the screw guide into the bone using the hand drill. While drilling, the hand drill should be held steady so that the drilling direction is maintained throughout the procedure. Once the second cortex has been reached, reduce the drilling speed; four more turns are needed so that the tip just protrudes through the distal cortex. In cancellous bone, there is no need for the tip of the screw to protrude from the second cortex. Diaphyseal Bone Screws should always be inserted in the center of the bone axis to avoid weakening it. In all cases the surgeon should be mindful of the amount of torque required to insert the screw. If it seems tighter than usual, it is safer to remove the screw and clean it, and drill the hole again with a 4.8mm drill bit, even if it has already been used.



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.



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



Screw Insertion After Pre-Drilling

Insert the 3.2mm or 4.8mm drill guide into the screw guide, and introduce a 3.2mm or 4.8mm 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. 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.

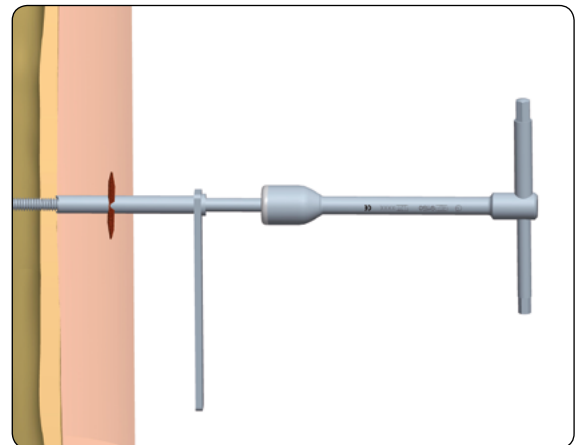
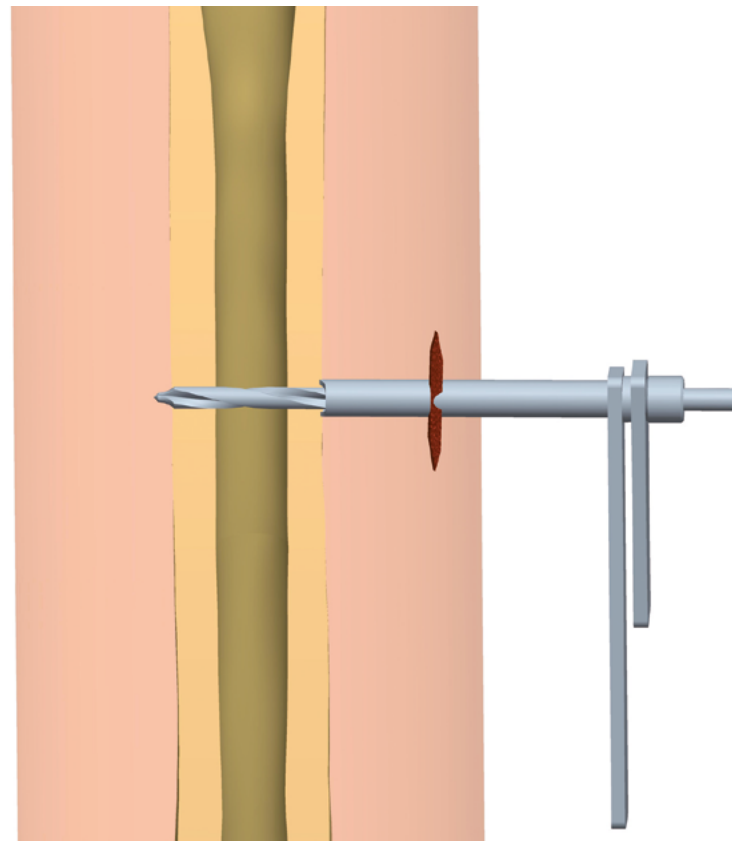
Remove the drill bit and drill guide, keeping pressure on the handle of the screw guide. The screw is inserted with the T-Wrench or hand drill until it reaches the second cortex. A further 4-6 turns are required to ensure that about 2mm of the screw protrudes beyond the second cortex.



WARNING: Do not excessively penetrate the second cortex with any type of screw 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.



Insert the remaining screws using the same technique. The two screws in each bone segment are joined by rods of suitable length, each one mounted with two screw clip clamps positioned about 20mm from the skin. They are then locked firmly with the 5mm Allen Wrench.

A third rod is then used to join the first two rods together by the rod clip 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 the two rod clip clamps firmly with the Universal T-Wrench or the 5mm Allen Wrench, while gripping them with the Clamp Holder (92017) to counter-act the tightening forces.



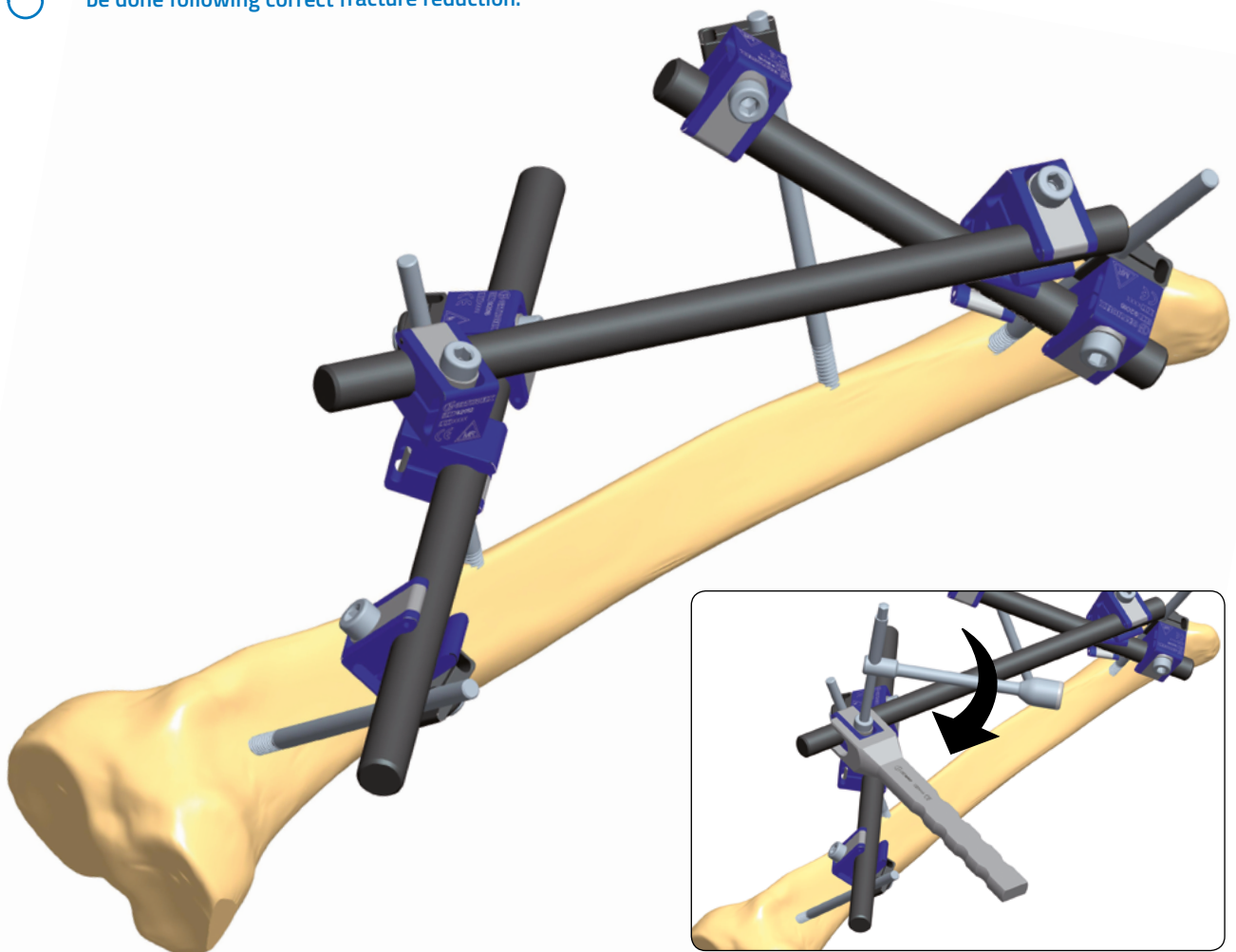
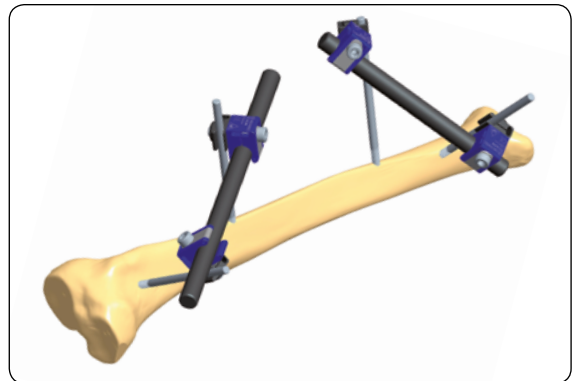
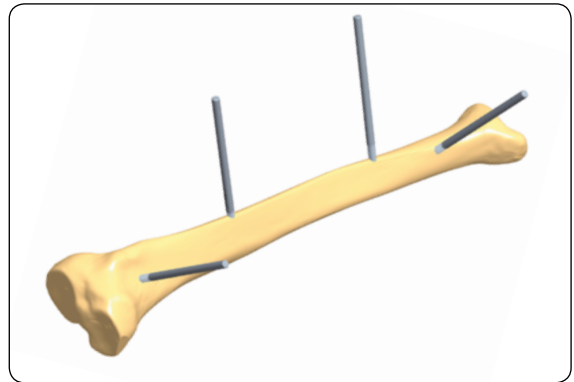
PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.



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.



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



The screw shafts are then cut with the Bone Screw Cutter. 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 20mm 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.



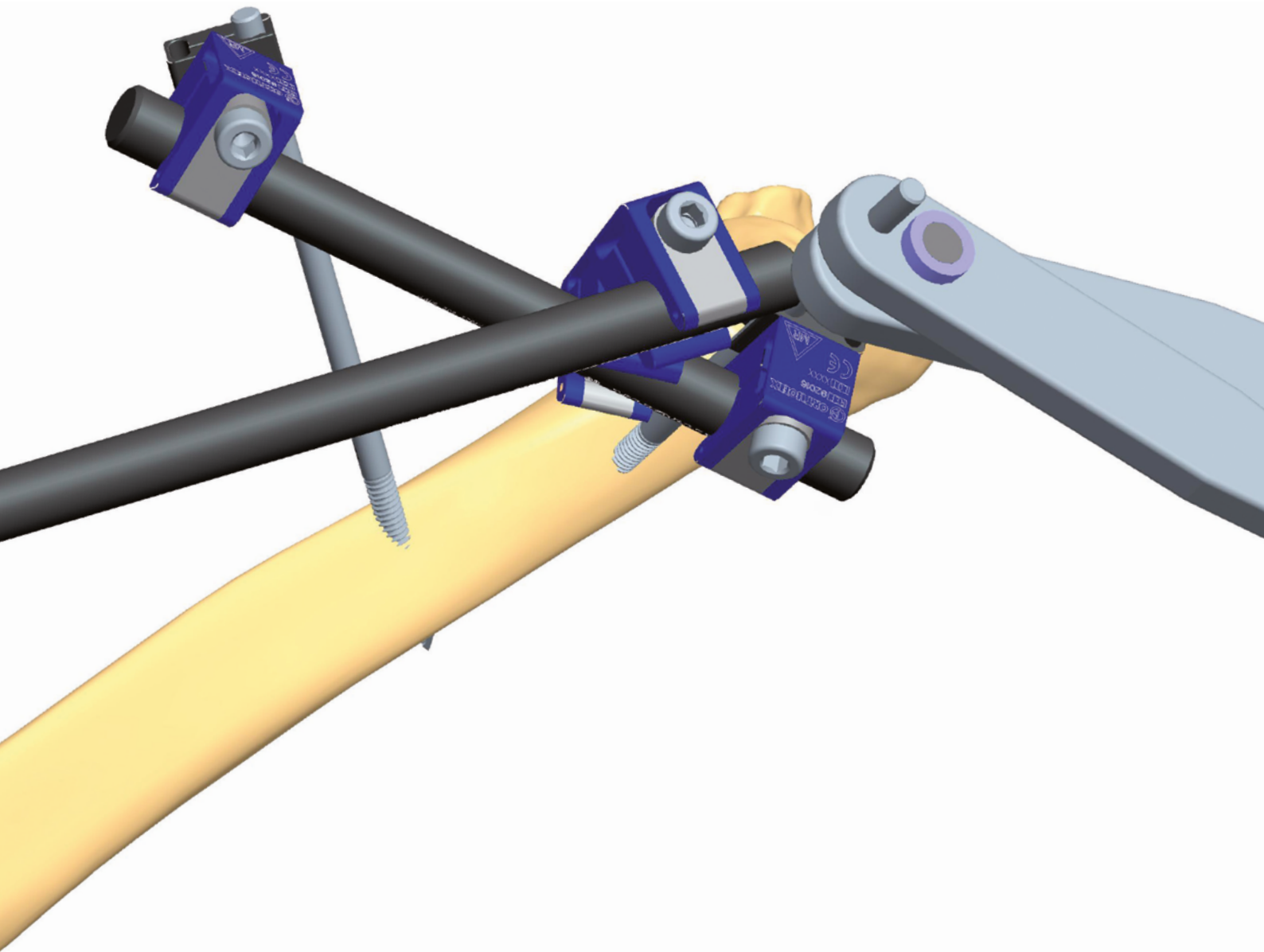
PRECAUTION: When using screws, avoid cutting after screw insertion without the fixator applied. Cutting inserted screws without the fixator applied could transfer the cutting force to the bone.



PRECAUTION: To avoid causing injury, the ends of screws or transfixing pins 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.



BLUE MULTI SCREW CLAMP

This clamp allows parallel screw positioning either in a T- or a straight clamp configuration. Note that the positions of the guide 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.

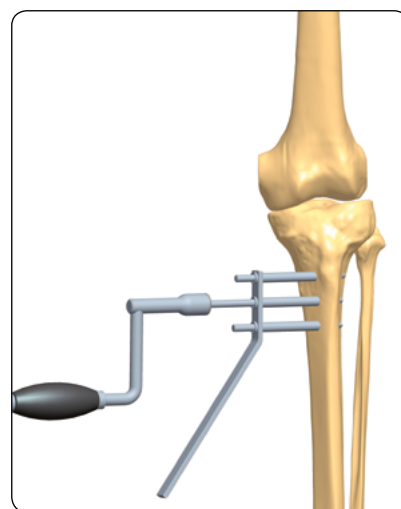
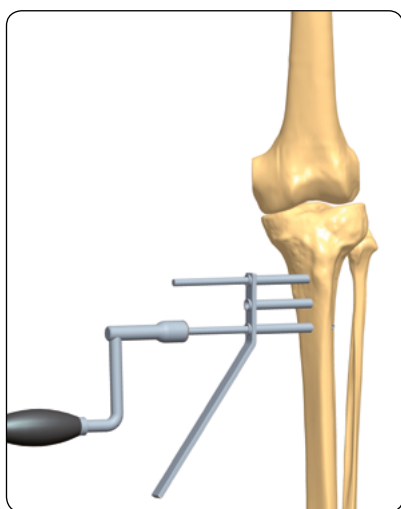
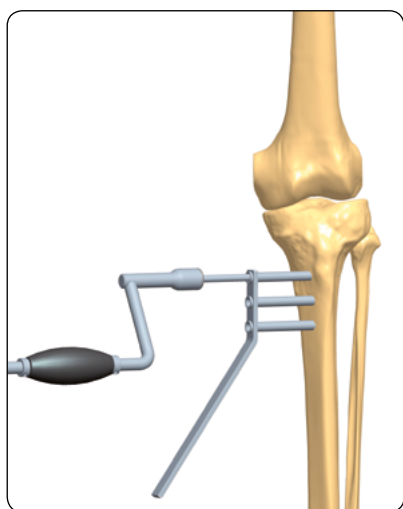
This clamp should be used when a later planned reconstructive procedure with the LRS might be anticipated. In this case, it is necessary that the screws are inserted perpendicular to the long axis of the bone. Whenever possible the pin groups on either side of the fracture should be inserted exactly from the same direction.



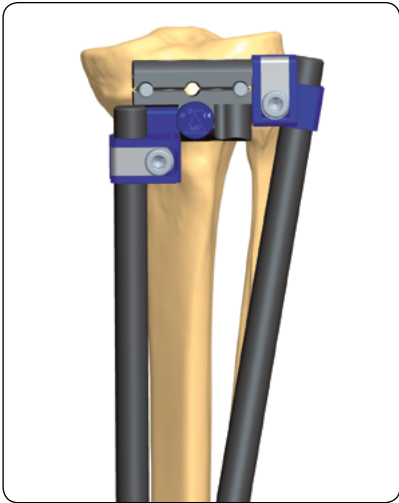
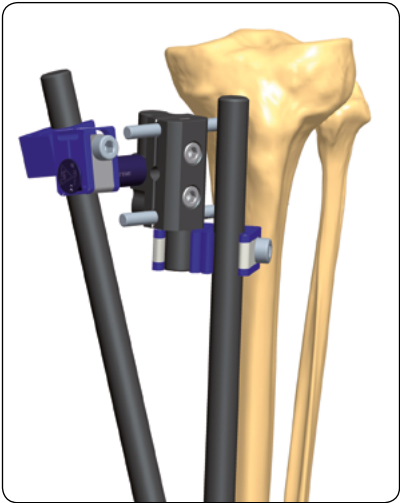
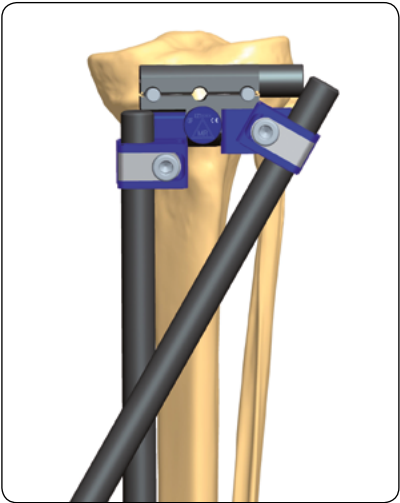
PRECAUTION: Diaphyseal Bone Screws and wires should always be inserted perpendicular to and in the center of the bone axis to avoid weakening it.

Reduce the fracture as anatomically as possible, emphasizing rotational correction. 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.

When using the Multi-Screw Clamp, two rods must always be used to increase frame stiffness.



Other possible connections



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: +39 045 6719301, fax: +39 045 6719370

e-mail: customerservice@orthofix.it

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



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