

## **GALAXY UNYCO™ DIAPHYSEAL TIBIA**

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## INTRODUCTION

Rapid skeletal stabilisation with external fixation is used for some severe high energy tibial fractures, especially in those with multiple injuries or from combat or natural disaster scenarios. This damage control surgery is part of a staged protocol where the temporary external fixation is an emergency procedure to be followed by definitive fracture fixation when conditions allow. In these scenarios, the external fixator has to be stable, versatile and quick to apply.

Tibia fractures with severe soft tissue injuries present several problems due to contamination, loss of soft-tissue support, and disruption of the periosteal blood supply (Maurer, Yokoyama, Bhandari). These fractures are associated with high rates of complications including deep infection (Papakostidis, Chua, Bhandari). The management of open tibial fractures continues to challenge orthopaedic, plastic and vascular surgeons (Chua).

The Galaxy UNYCO™ (Galaxy UNYCO hereinafter) Diaphyseal Tibia Sterile Kit is an external fixation system conceived for temporary stabilization of tibial fractures, achieving excellent stability but without the screws perforating the medullary canal. The whole system offers the following unique benefits:

For the patients:

- Designed to avoid contamination of the medullary canal
- Designed for a minimally invasive approach
- Designed to facilitate the conversion from temporary to definitive fixation

For the surgeons:

- Fewer steps in the operative technique
- Designed to facilitate the conversion from temporary to definitive fixation
- Designed to avoid contamination of the medullary canal
- Completely compatible with the Galaxy External Fixator System, thereby enabling additional injuries of the lower limb to be stabilised and linked to the UNYCO assembly
- Simplicity in application enabling rapid familiarity and mastery of the system

For the hospital:

- Designed to allow a minimally invasive approach that may optimize OR time and result in cost savings

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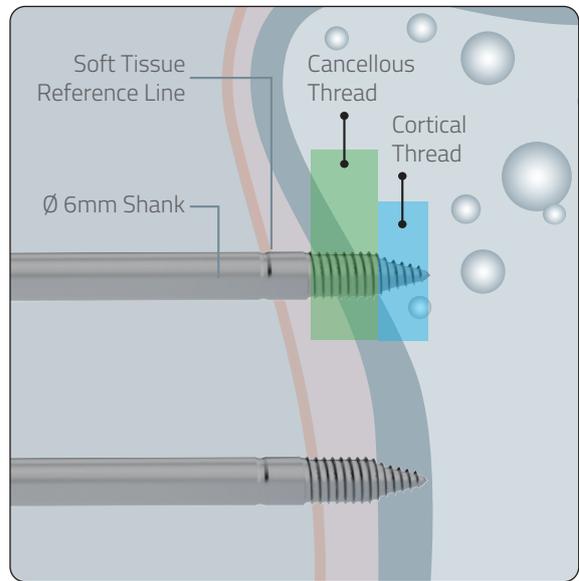
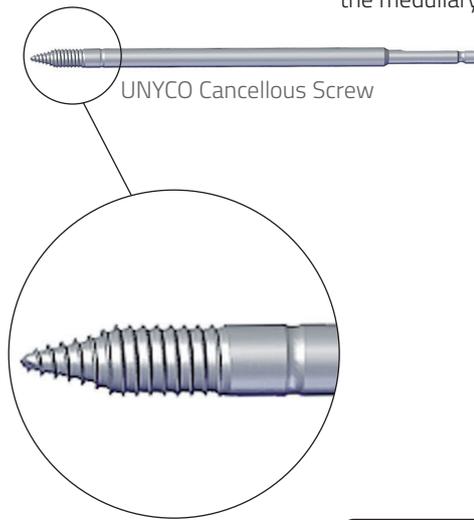
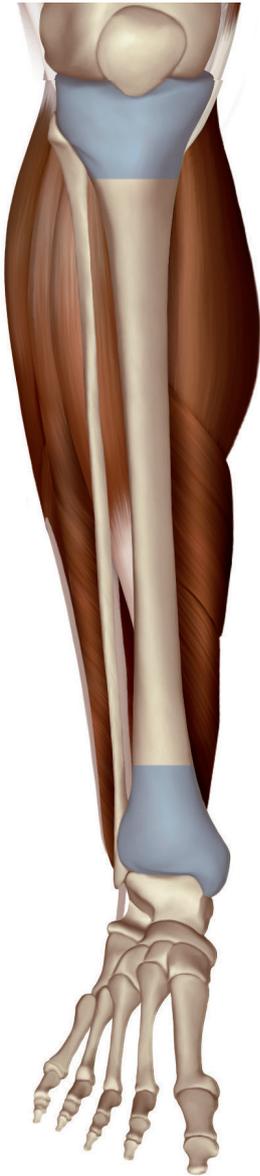
Please kindly refer to the product IFU PQUNY, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

### MAIN FEATURES



Part#	Description
93508	UNYCO Cancellous Screw QC Shaft Ø 6mm

UNYCO Cancellous Screw is designed for both diaphyseal and metaphyseal bone. The screw has a 6mm Ø shaft, is made of surgical grade stainless steel and is conical. The cortical thread is 5mm long, whereas the cancellous thread is 10mm long (so, the UNYCO Cancellous Screw thread is 15mm long). The special thread and tip design will only require screw insertion into the first cortex of the bone, avoiding perforation of the medullary canal.

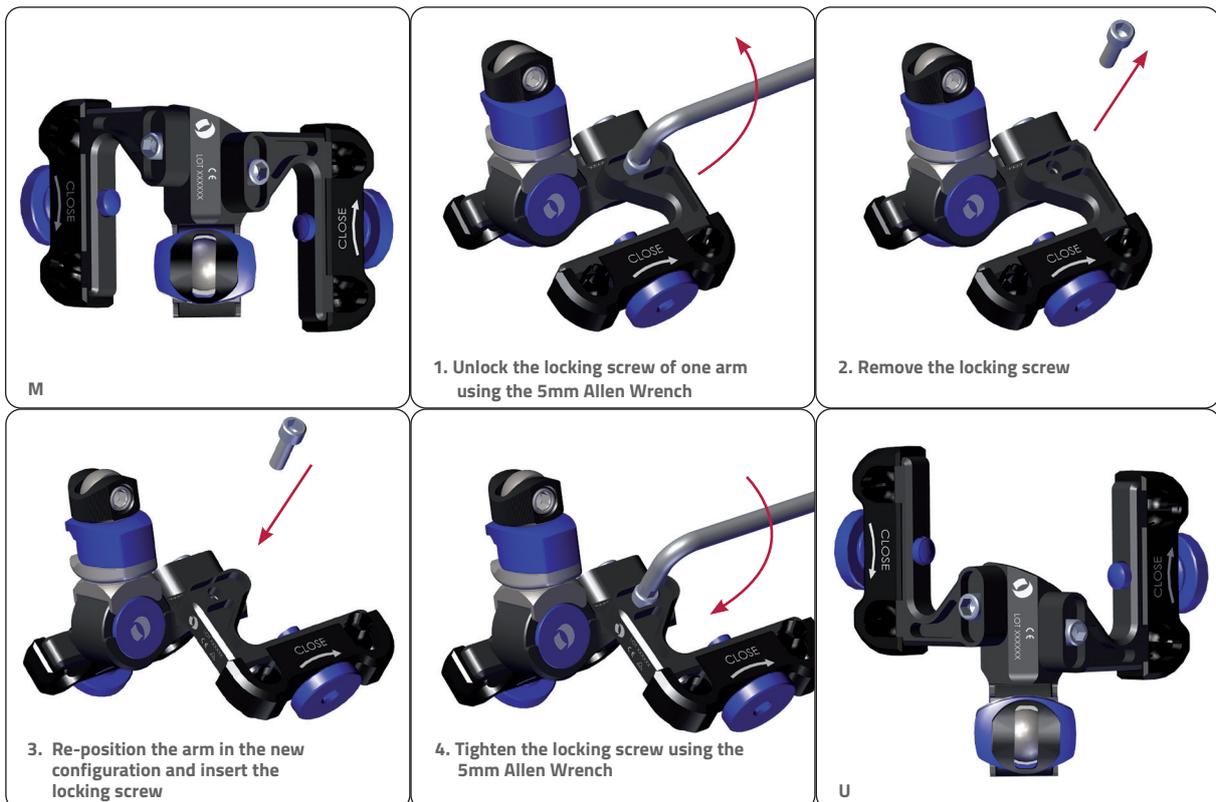




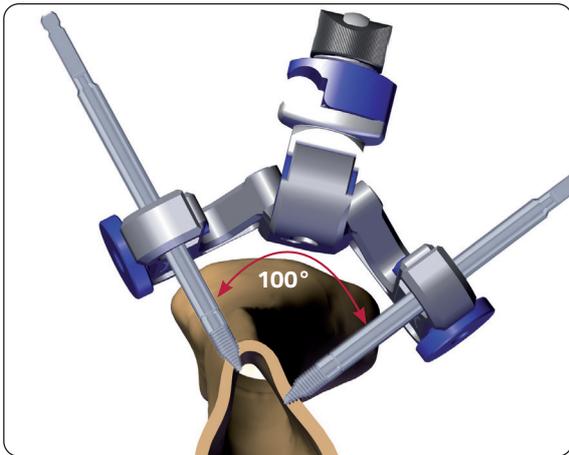
### Large Multiscrew Clamp for UNYCO Screws

The clamp is provided in M configuration, but it can be easily converted to U configuration by unlocking the arms with the universal Allen Wrench and by re-positioning them (see below). This feature makes the system flexible and versatile.

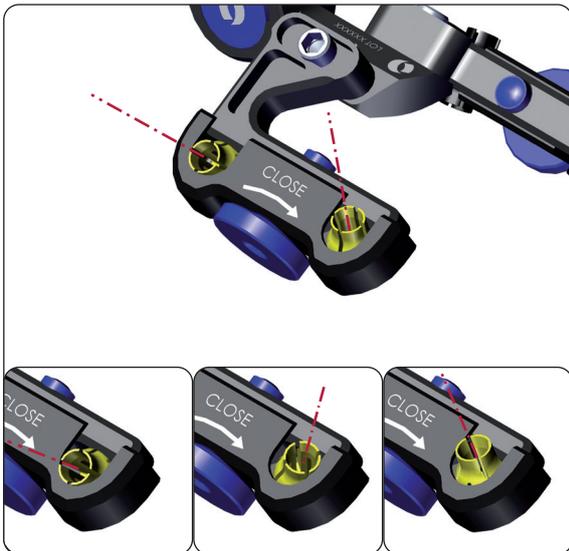
How to change configuration



Repeat the above mentioned steps 1-4 to position the second arm.



The two arms subtend a 100 degree arc, which facilitates screw insertion perpendicular to the bone surface.



The screw seats allow  $\pm 10^\circ$  variable angle screw positioning so that screws can be oriented independently.

## EQUIPMENT REQUIRED

Part#	Description	Qty
99-93794	Galaxy UNYCO Diaphyseal Tibia Box	
can accommodate:		
99-93574	Galaxy UNYCO Mini Kit Tibia Sterile	2
99-932350	Rod D12mm L 350mm Sterile	1
99-93509	Galaxy UNYCO Mini Kit Instruments Sterile	2



99-93574 - Galaxy UNYCO Mini Kit Tibia Sterile



99-93567 - Limited Torque Wrench  
(out of Kit - available upon request)

For manual screw insertion.



99-93509 - Galaxy UNYCO Mini Kit Instruments Sterile

## UNI-CORTICAL SCREW INSERTION

Make a 5mm puncture in the skin.  
(Fig. 1)

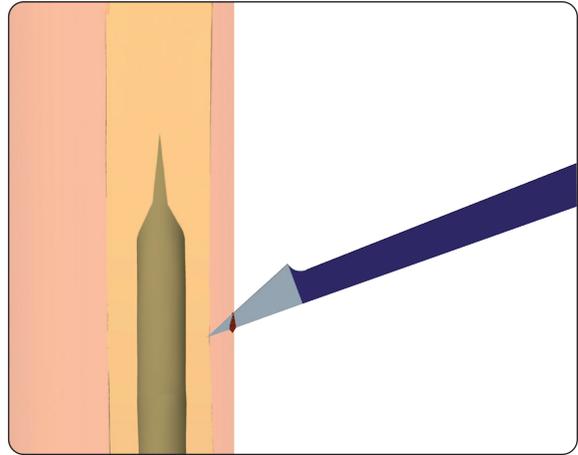


Fig. 1

Insert the first screw freehand, without the clamp, directly over the tibial crest (Fig. 2a) medial or lateral (Fig. 2b) to it and check its correct position on the bone. Always attempt a perpendicular placement of the screw on the bone surface.

**PRECAUTION:** Uni-cortical screws must be inserted perpendicular to the bone surface using low rotation speed and a steady thrust to ensure optimal bone purchase.

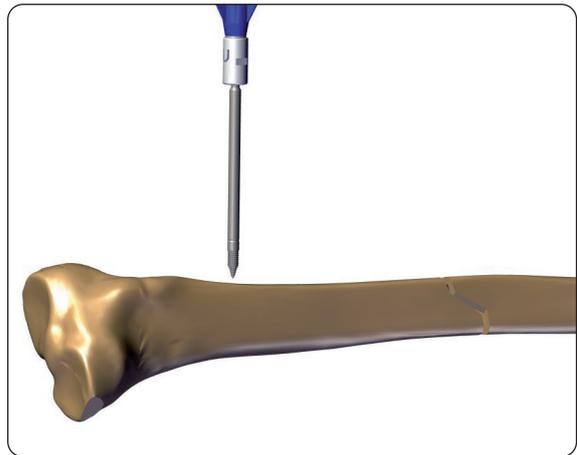


Fig. 2

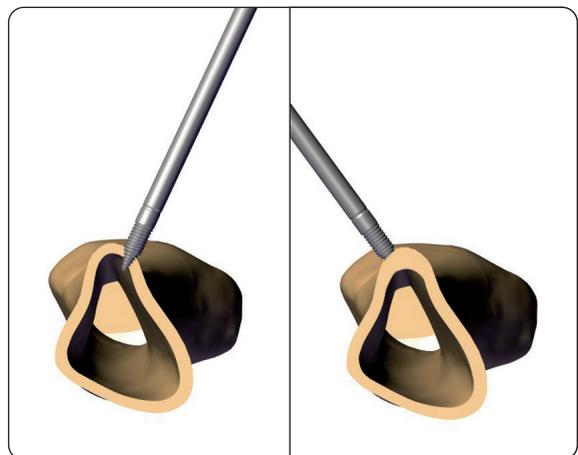


Fig. 2a

Fig. 2b

### Screw Insertion

Drill the screw perpendicular to the bone surface using a low speed power drill with the Power Drill Torque Limiter already mounted.

The depth of insertion by the UNYCO Cancellous Screw in cancellous bone is controlled by the surgeon who stops advancing the drill when the reference line of the screw shank is flush with the skin surface. (Fig. 3a)

There will be instances when the cortex of cancellous bone is sufficiently hard that the torque limiter will activate and decouple the drilling and therefore stop further unnecessary advancement of the screw.

The depth of penetration of the cortex of diaphyseal bone by the UNYCO Cancellous screw is controlled by the torque limiter. The torque limiter decouples the drill when the required torque has been reached. (Fig. 3b)

**PRECAUTION:** Uni-cortical screws must be inserted perpendicular to the bone surface using low rotation speed and a steady thrust to ensure optimal bone purchase.

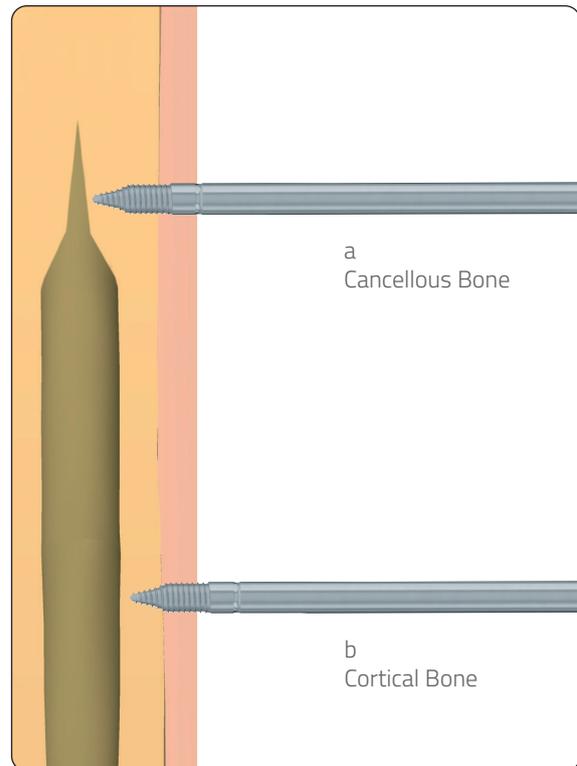


Fig. 3

Apply the Large Multiscrew Clamp (93566) on the first screw and tighten the metal ring on the arm clockwise. (Fig. 4)

**PRECAUTION:** Once converging uni-cortical screws have been inserted, the distance of the clamp from the soft tissue surface cannot be altered. It is therefore important to determine the final distance of the fixator from the skin before inserting the second screw in the clamp.

The clamp should be positioned at a distance of 40mm from the skin.

(Fig. 4)

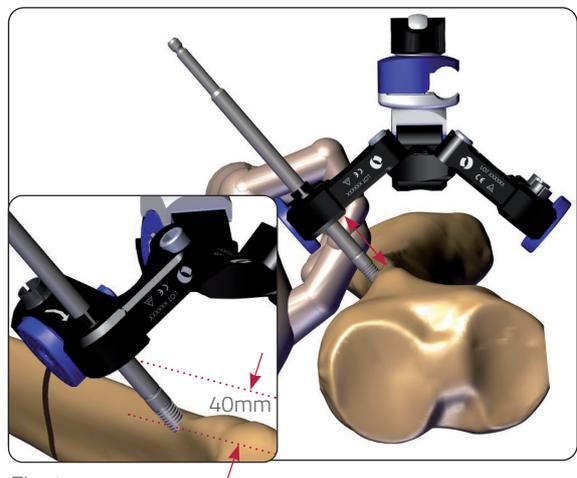


Fig. 4

Using the Large Multiscrew Clamp (93566) as a template for screw insertion, insert the second screw in the contralateral arm, trying to be as perpendicular as possible to the bone surface. Check its correct position on the bone and if necessary partially tighten the metal ring on the arm clockwise so that the screw within its seat is free to move but without excessive play. (Fig. 5)

**PRECAUTION:** Uni-cortical screws must be inserted perpendicular to the bone surface using low rotation speed and a steady thrust to ensure optimal bone purchase.

**PRECAUTION:** During and after insertion, ensure correct positioning of the implants under image intensification. Check screw insertion both in the AP and lateral planes.

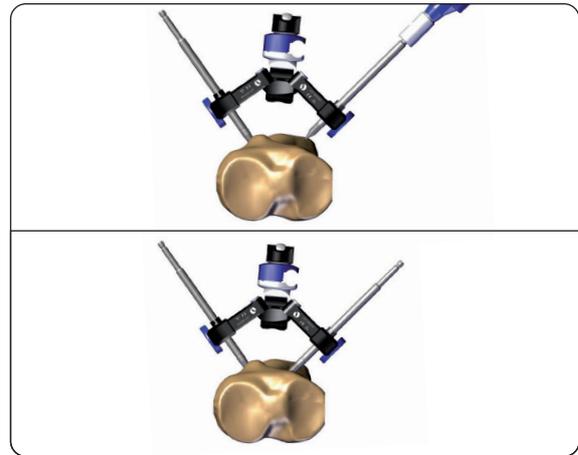


Fig. 5

The clamp should not be pulled/pushed after the second screw is inserted. (Fig. 6)

**PRECAUTION:** During and after insertion, ensure correct positioning of the implants under image intensification. Check screw insertion both in the AP and lateral planes. (Fig. 8)

**PRECAUTION:** The system stability is guaranteed only with 4 UNYCO screws coupled with the Large Multiscrew Clamp in each segment. The Large Multiscrew Clamp for UNYCO Screws should never be applied across the fracture line.

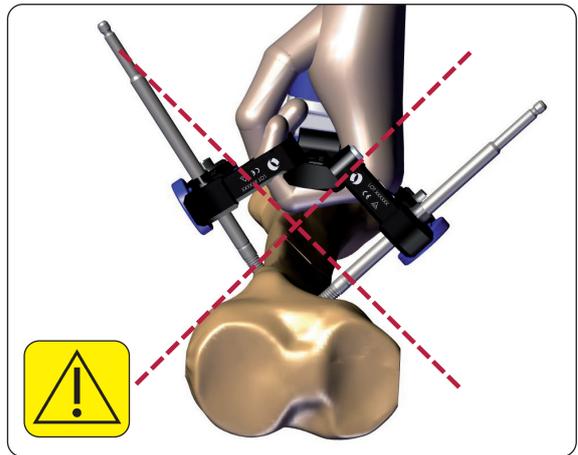


Fig. 6

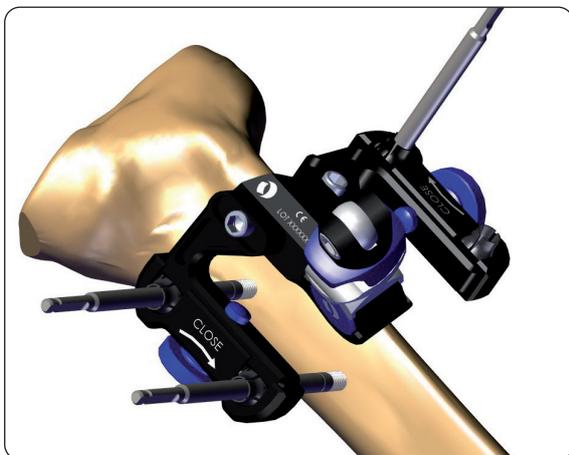


Fig. 7

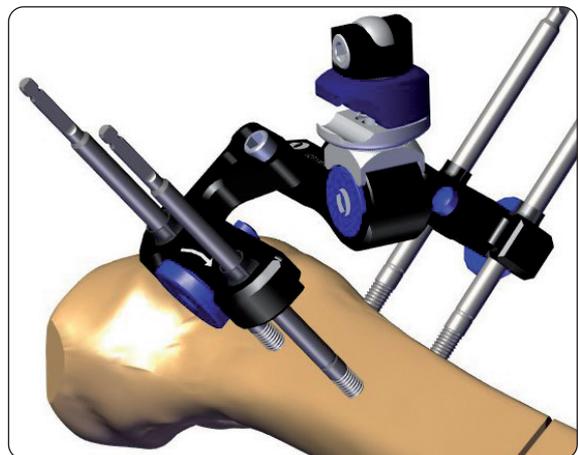


Fig. 8

Once all screws in each arm have been inserted, tighten both metal rings fully with the 5mm Allen Wrench (30017). (Fig. 9)

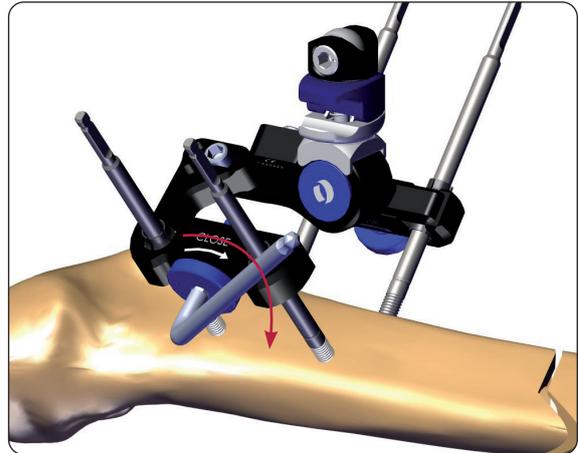


Fig. 9

Follow steps 2-5 to apply the second Large Multiscrew Clamp in the distal segment. (Fig. 10)

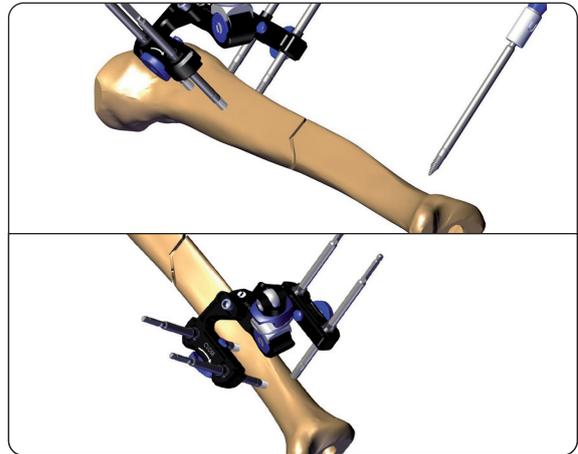


Fig. 10

Join both Large Multiscrew Clamps with the rod leaving the clamps loosened to facilitate fracture reduction. (Fig. 11)

**PRECAUTION:** Ensure there is a sufficient length of Rod on either side of both proximal and distal clamps so as to enable reduction maneuvers that may require distraction (lengthening) between the two clamps.



Fig. 11

Reduce the fracture, with X-ray guidance as necessary, holding the clamps to facilitate the reduction maneuver. (Fig. 12)

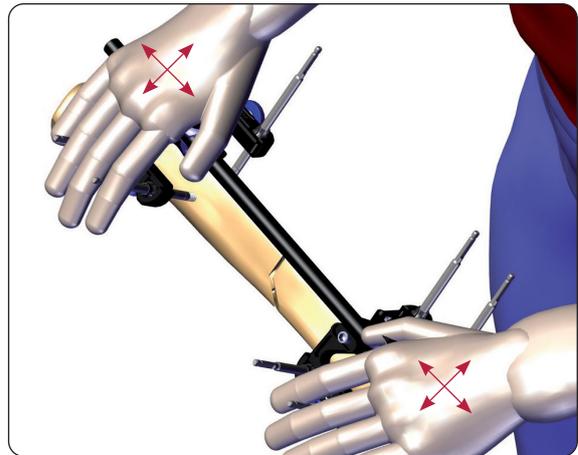


Fig. 12

Lock the clamps first manually by turning the knurled metal ring clockwise. (Fig. 13)

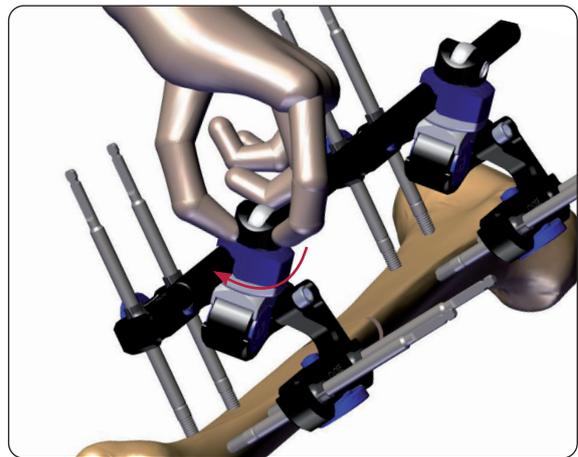


Fig. 13

If reduction is satisfactory, finally lock all the clamps firmly by tightening the cams with the 5mm Allen Wrench. (Fig. 14)

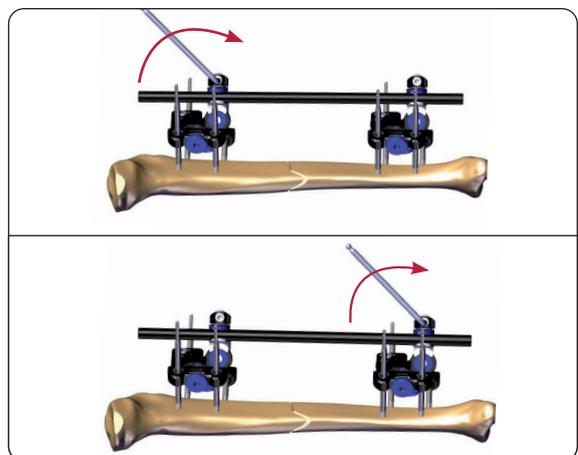


Fig. 14

**WARNING:** If faced with a segmental fracture, the intermediate segment can be held using additional uni-cortical screws in different planes in GALAXY FIXATION Large Clamps attached to the connecting rod.

Before drilling the UNYCO Cancellous Screw into the bone, partially tighten the metal ring on the clamp clockwise so that the screw within its seat is free to move but without excessive play. Once the screw has been inserted, tighten the clamp by hand.

(Fig. 15)

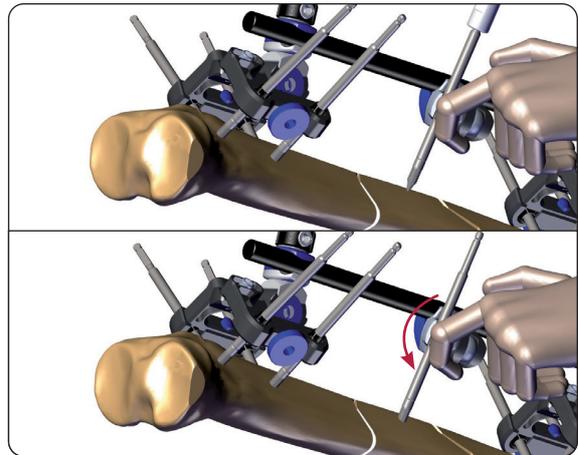


Fig. 15

Finally, lock the clamp with the Allen Wrench (30017).  
(Fig. 16)

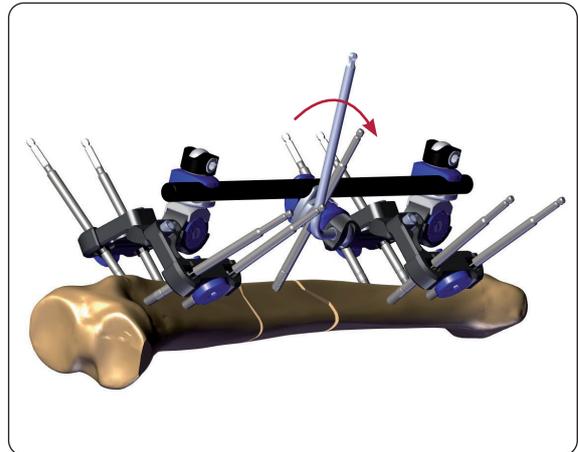


Fig. 16

CHANGING TO DEFINITIVE TREATMENT

If the system is perceived as impediment for the correct definitive treatment application, remove the SYSTEM PARTS where needed. For instance, if there was a need to insert a plate on the medial side but maintain the overall reduction and alignment:

Unlock the metal ring of the medial arm of the proximal Large Multiscrew Clamp.  
(Fig. 17)

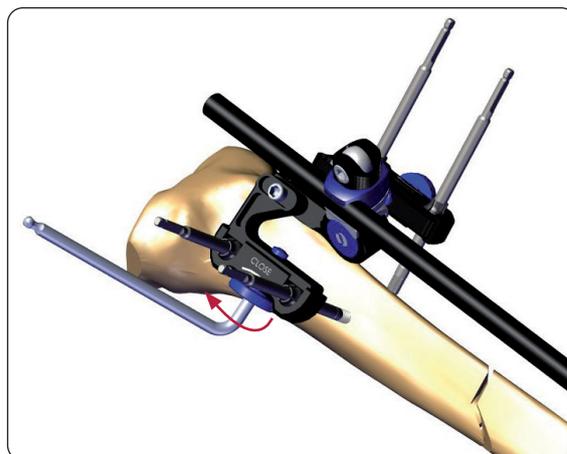


Fig. 17

Remove the uni-cortical screws.  
(Fig. 18)

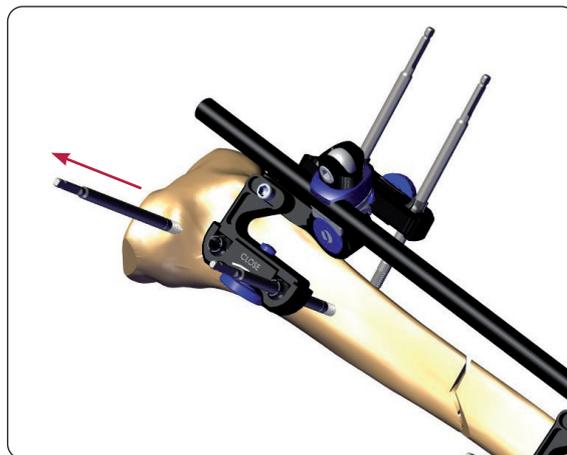


Fig. 18

Unlock the locking screw of the medial arm with the 5mm Allen Wrench.  
(Fig. 19)

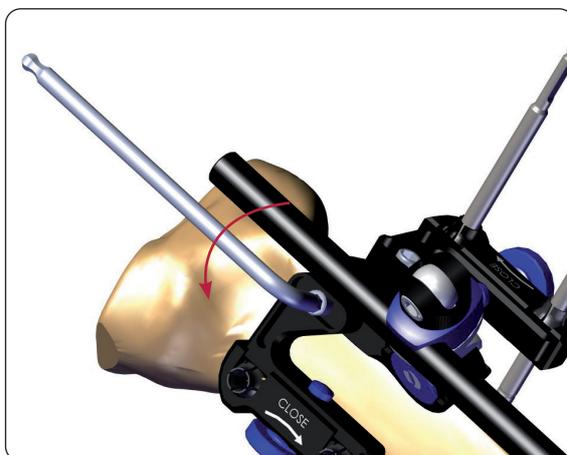


Fig. 19

Remove the medial arm.  
(Fig. 20)

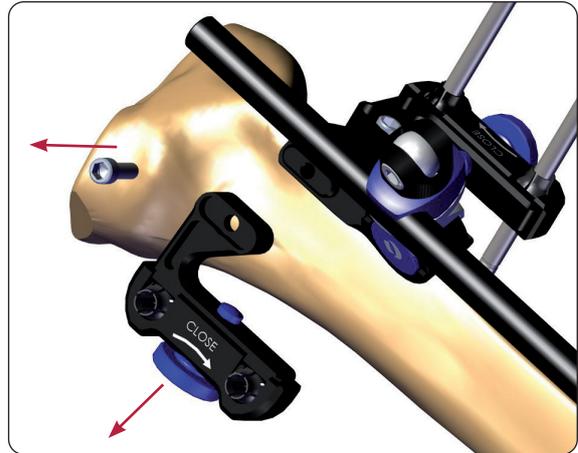


Fig. 20

If necessary repeat the procedure with the distal clamp.  
(Fig. 21)

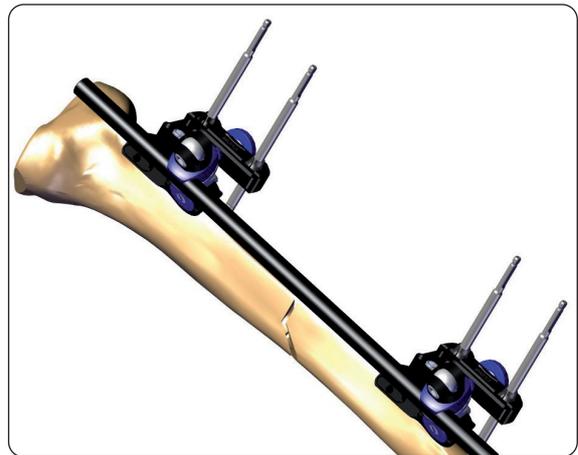
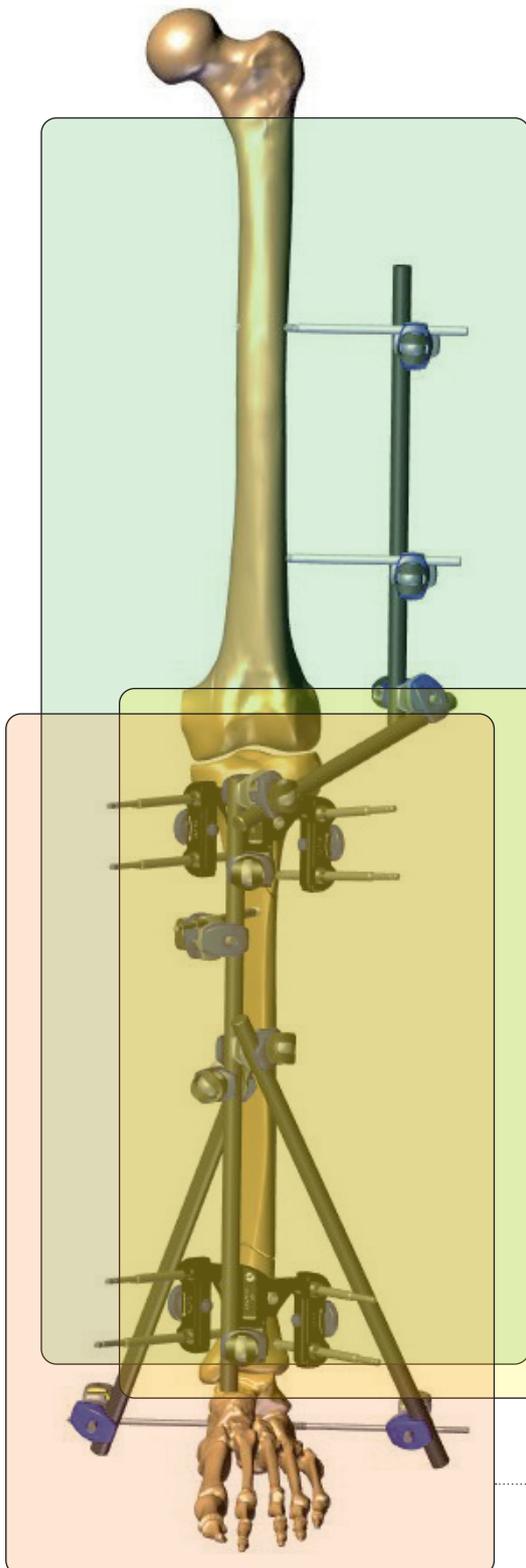


Fig. 21

In a similar fashion, if lateral submuscular plating was intended for the fracture, the lateral arms could be removed instead. In both scenarios described above, it is imperative there are 4 screws in each Large Multiscrew Clamp before any arm is disconnected.

If intramedullary nailing of the fracture is envisaged as definitive treatment, it is usually not necessary to remove the fixator at all. However, appropriate sterile precautions would need to be taken to seal off the fixator from the remainder of the operative field.

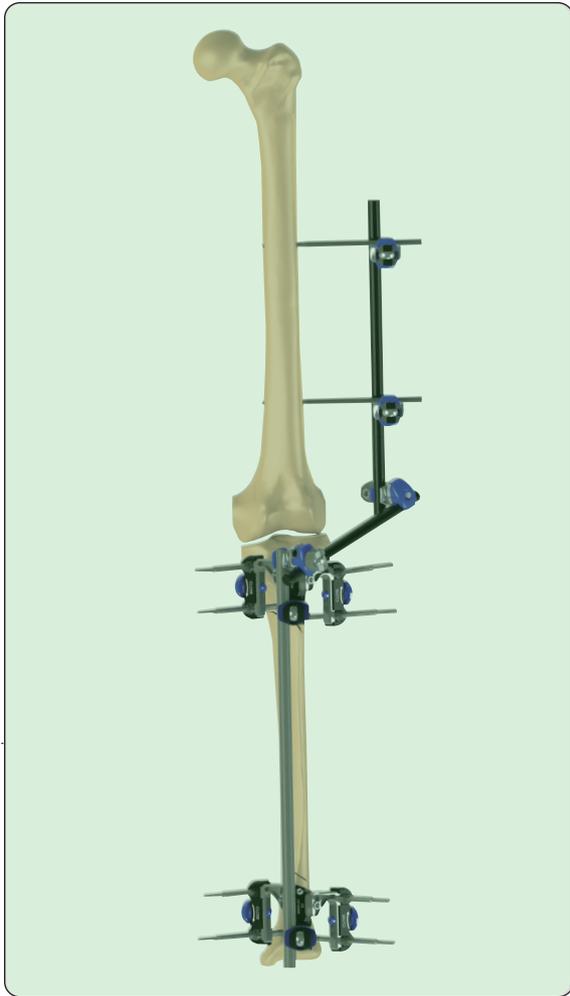
DAMAGE CONTROL



Knee spanning configuration for peri-articular fractures or ligamentous injuries of the knee

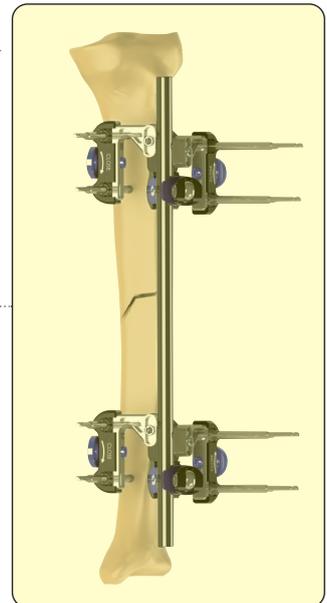
Tibial application for peri-articular, diaphyseal or segmental fractures (as shown)

Ankle spanning configuration for peri-articular fractures or ligamentous injuries



Knee spanning configuration for proximal tibial fracture associated with ligamentous instability of the knee

Standard configuration for mid-shaft fracture of the tibia



UNILATERAL FRAME



DELTA FRAME



Ankle spanning configuration for distal tibial fracture associated with ankle joint instability





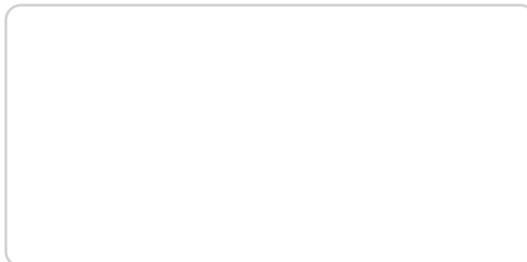
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