

GALAXY UNYCO™ DIAPHYSEAL TIBIA

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Orthofix wishes to thank
the following surgeons for their contribution
to the development of the technique:

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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 continue to challenge orthopaedic, plastic and vascular surgeons (Chua).

The Galaxy UNYCO 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
- In case of polytrauma and emergency situations, quick fracture stabilization procedures may positively influence lifesaving outcomes

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 which may optimize OR time and result in cost savings
- Prepacked sterile kits enabling efficient inventory management, better traceability and reduced logistic costs

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INTENDED USE

The Galaxy UNYCO System is intended to be used for temporary bone stabilization in trauma and orthopedic procedures of the lower limb prior to definitive treatment.

INDICATIONS

Temporary stabilization of the tibia in conditions and procedures, such as:

- Comminuted open or closed tibial fractures extending from about 8cm below the knee to about 7 cm above the ankle joint
- Polytrauma patient
- Damage control orthopedics for fractures with severe soft tissue injuries
- Peri-prosthetic or peri-implant fractures
- Joint dislocations, intra- and extra-articular injuries where spanning fixation is needed
- Intra-operative fracture reduction
- Intermediate stabilization in staged surgery
- Infected non-union pending second stage treatment, bone-loss or other reconstructive procedures

The Galaxy UNYCO System is compatible with Galaxy Fixation System and bicortical screws. Galaxy Fixation System and bicortical screws must be used when Galaxy UNYCO is not indicated or available.

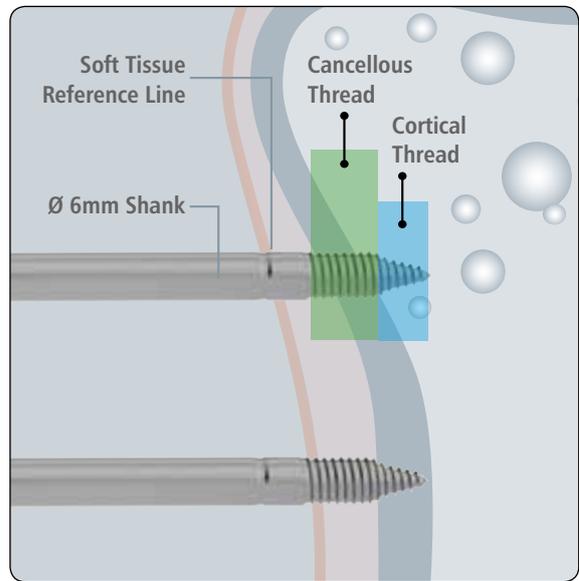
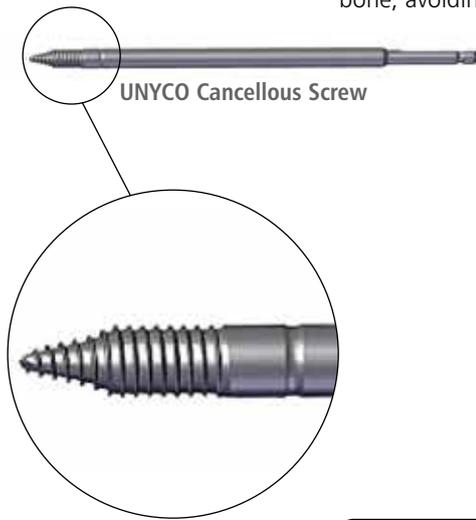
The product is indicated for non-weight-bearing use.

MAIN FEATURES



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

UNYCO Cancellous Screw is designed both for 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.

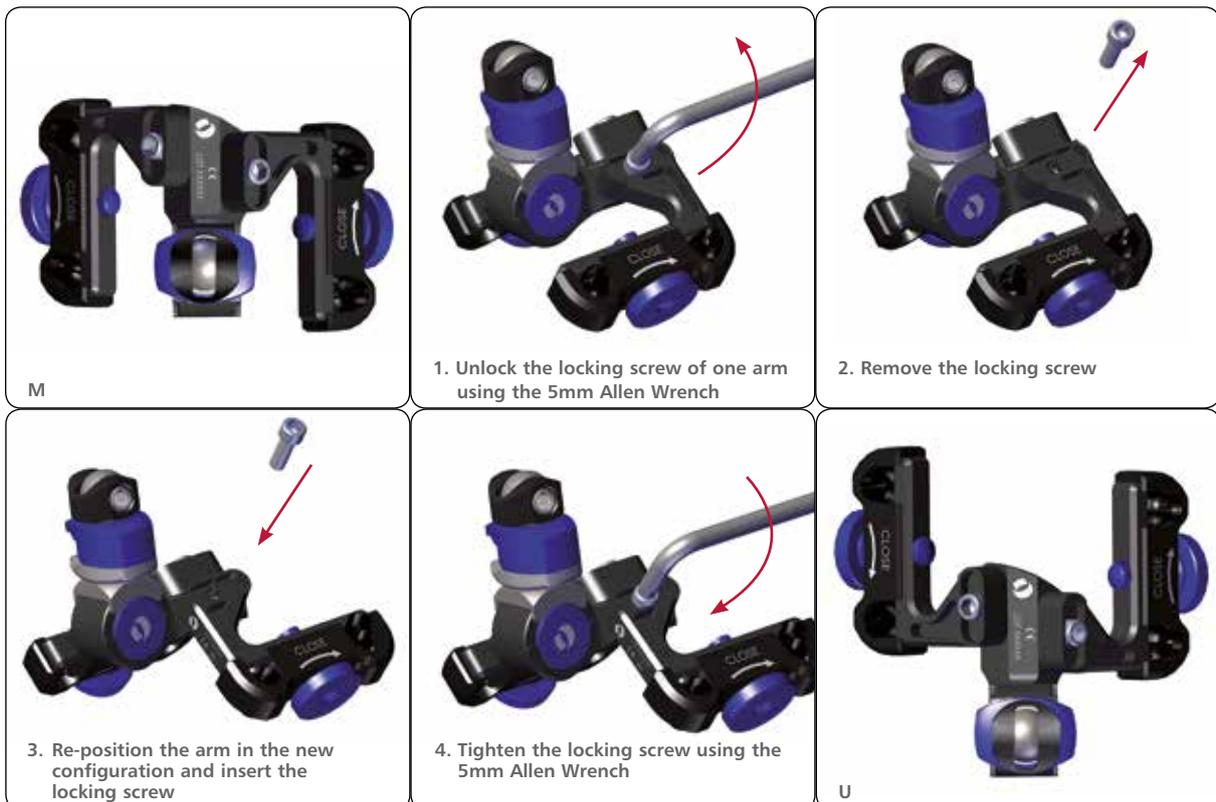




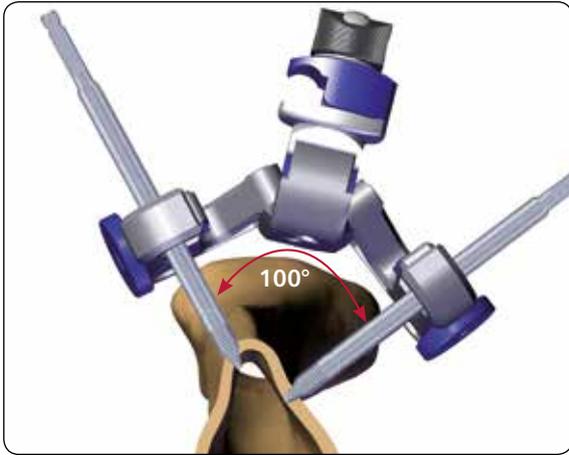
Large Multiscrew Clamp for UNYCO Screws

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	1



99-93574 - Galaxy UNYCO Mini Kit Tibia Sterile

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

To be used for inserting the screws by hand.



99-93509 - Galaxy UNYCO Mini Kit Instruments Sterile

UNI-CORTICAL SCREW INSERTION

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

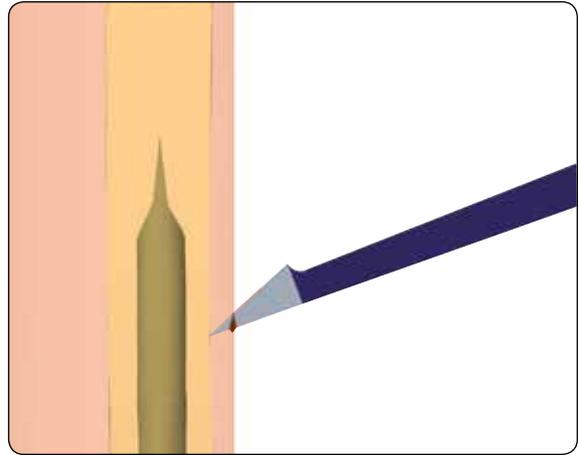


Fig. 1

Insert the first screw freehand, without the clamp, directly over the tibial crest (Fig. 2a) or 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.



Fig. 2

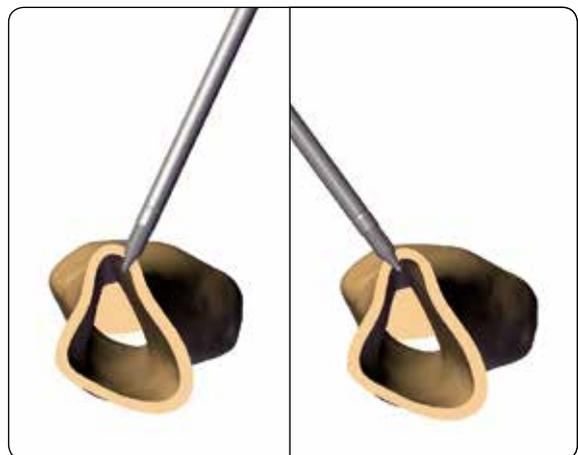


Fig. 2a

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)

(Fig. 3b)

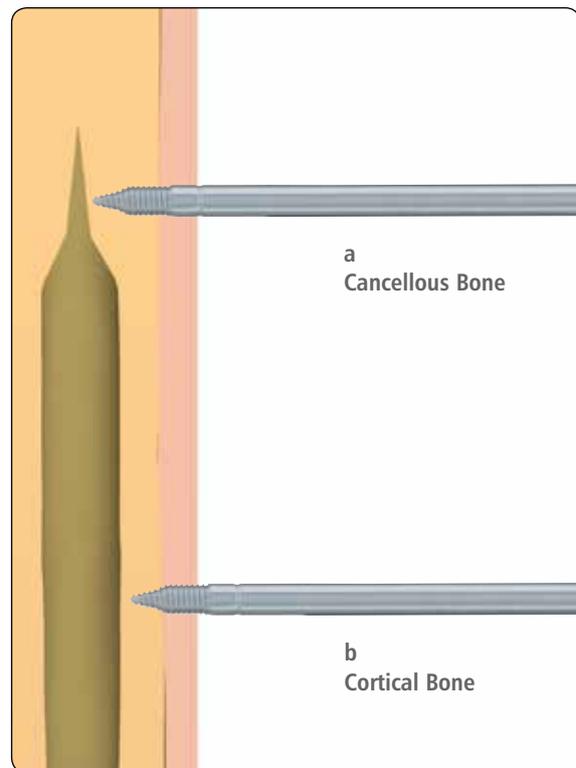


Fig. 3

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

NOTE: Once converging screws have been inserted, the clamps can no longer slide on the screw shafts. It is therefore important to determine the final distance (of 40mm or approximately 2 fingers breadth) of the clamp from the skin before inserting the second screw. Ideally, the clamp should be positioned at a distance of 40mm from the skin.

(Fig. 4)

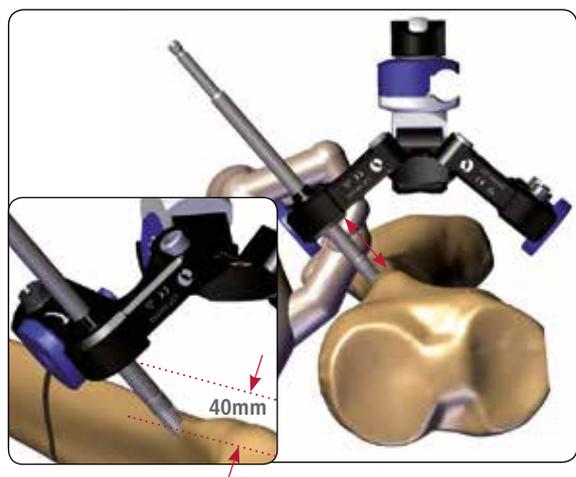


Fig. 4

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)

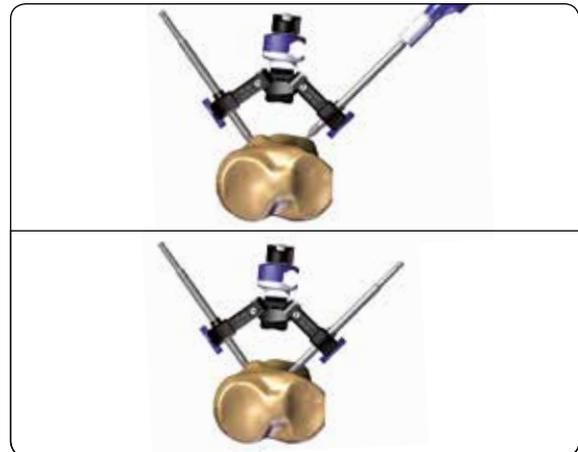


Fig. 5

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

WARNING: On the tibia, the system stability is guaranteed only with 4 screws coupled with the Large Multiscrew Clamp in each bone segment. (Fig. 8)

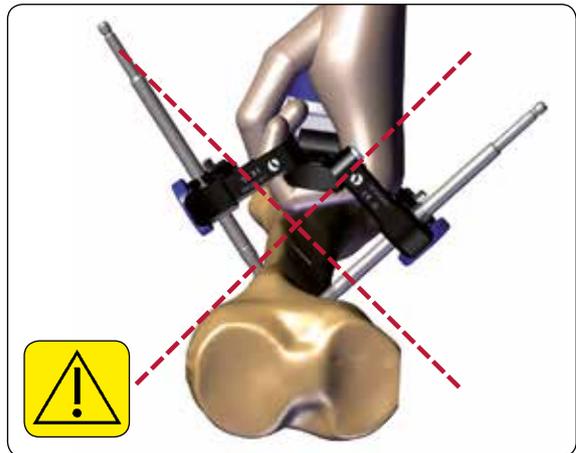


Fig. 6



Fig. 7

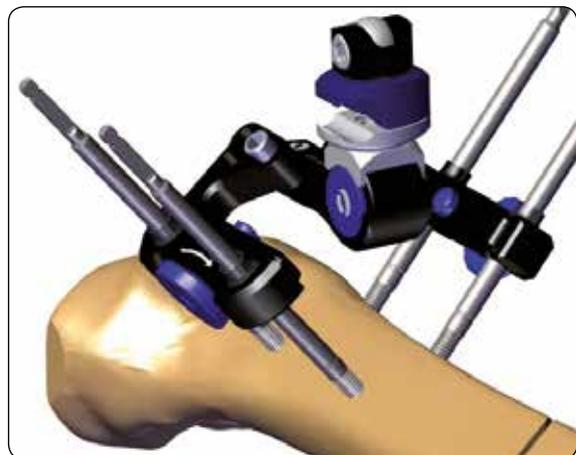


Fig. 8

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)

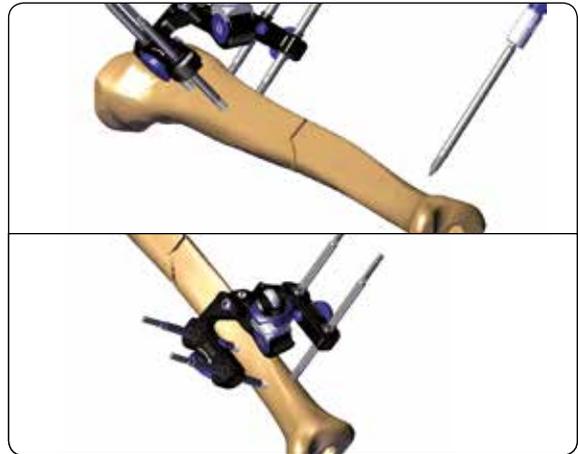


Fig. 10

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



Fig. 11

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

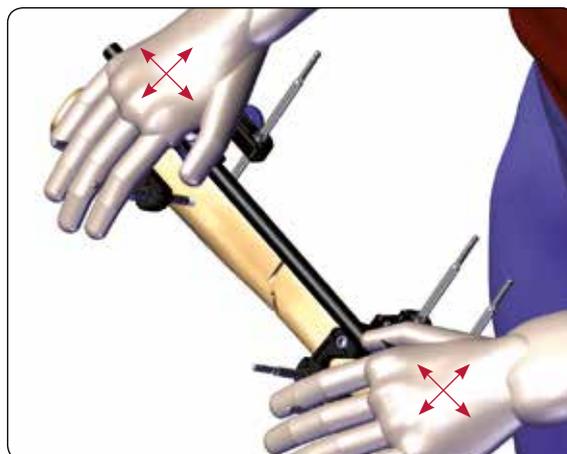


Fig. 12

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

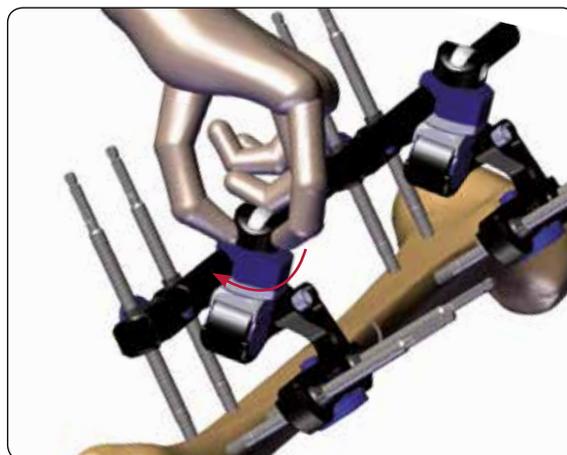


Fig. 13

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

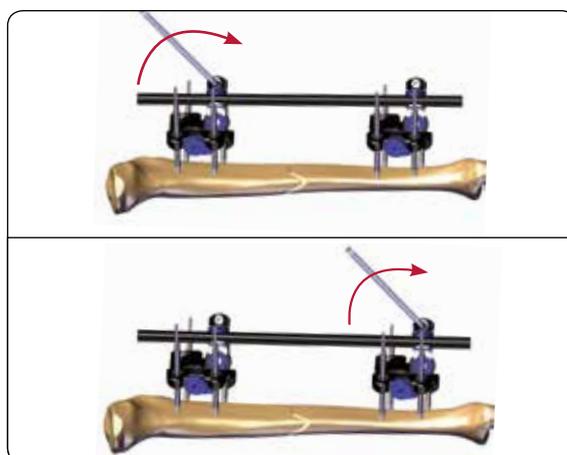


Fig. 14

In case of a segmental fracture, the middle segment can be stabilised using a UNYCO Cancellous Screw in a Galaxy Large Clamp (93010) attached to the same connecting rod that links the two Large Multiscrew Clamps.

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)

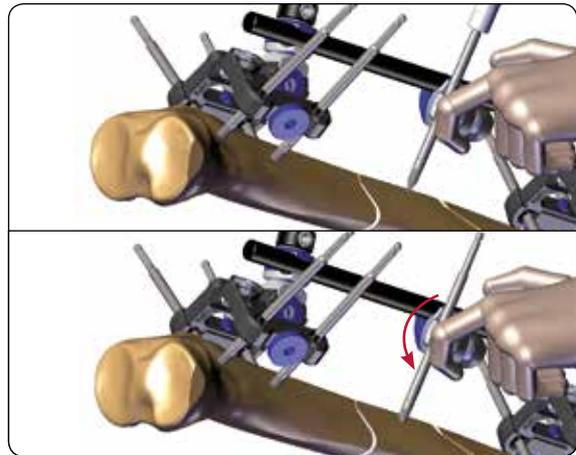


Fig. 15

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

(Fig. 16)

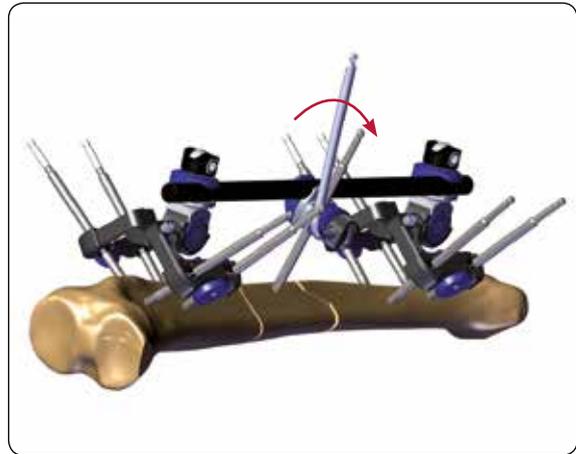


Fig. 16

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)

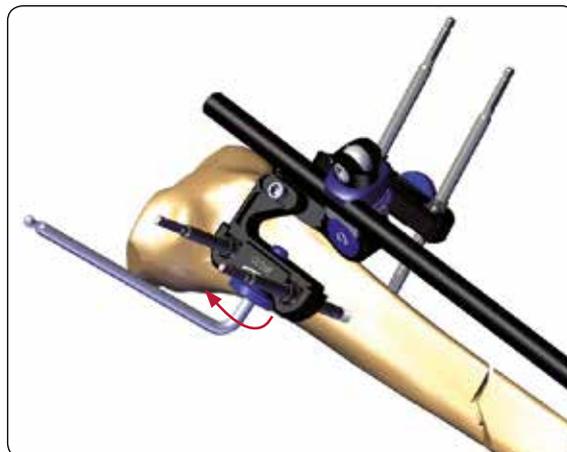


Fig. 17

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

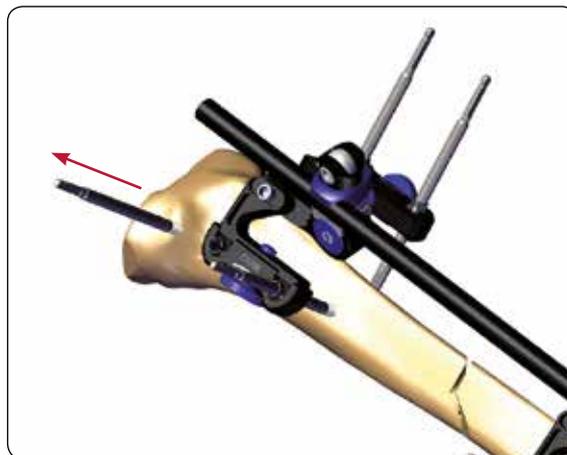


Fig. 18

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

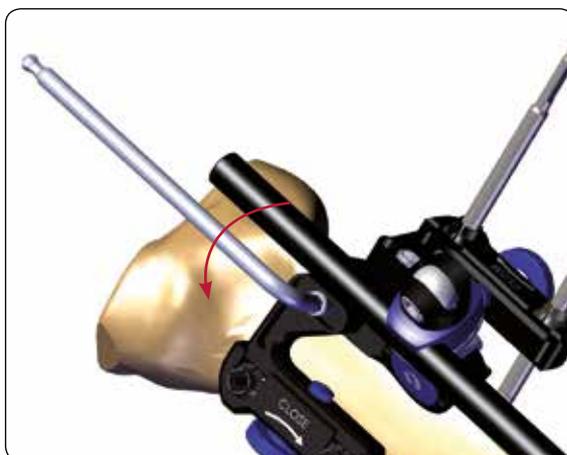


Fig. 19

Remove the medial arm.
(Fig. 20)

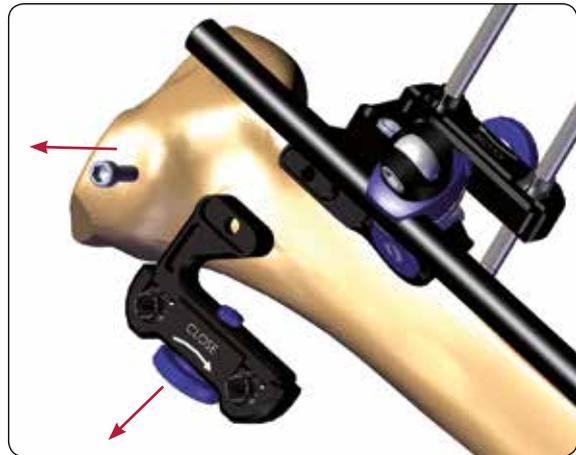


Fig. 20

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

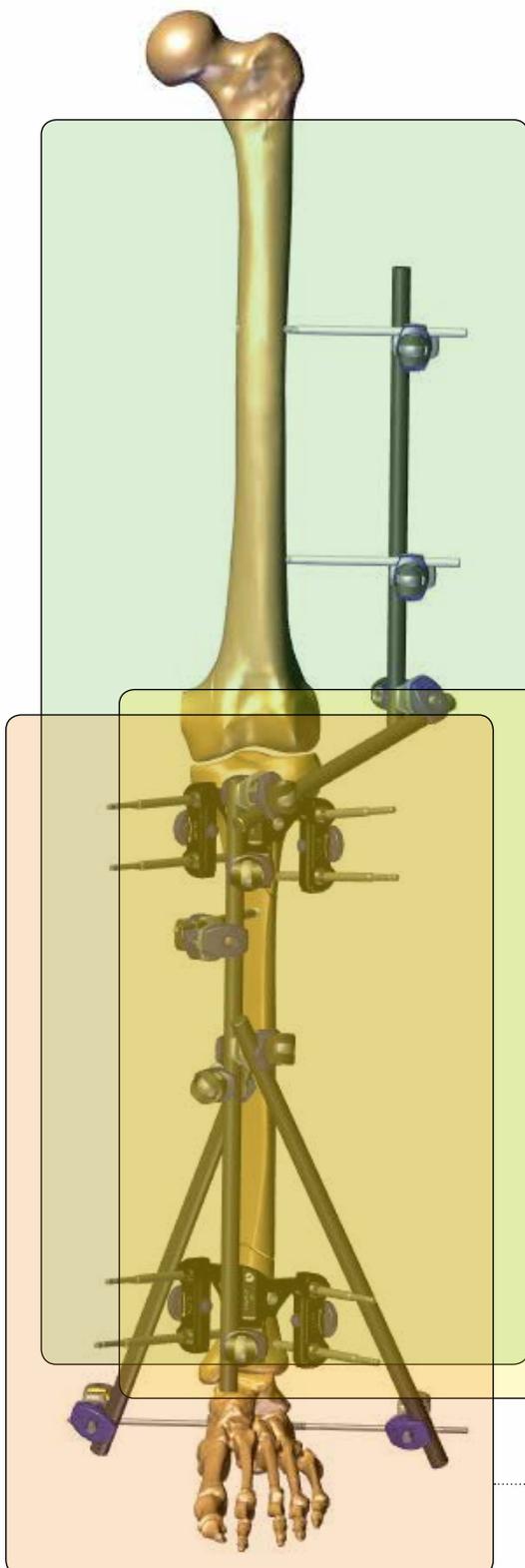


Fig. 21

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

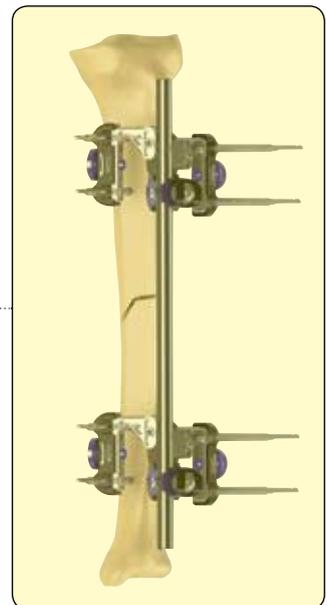
Tibial application for peri-articular, diaphyseal or segmental fractures (as shown)

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



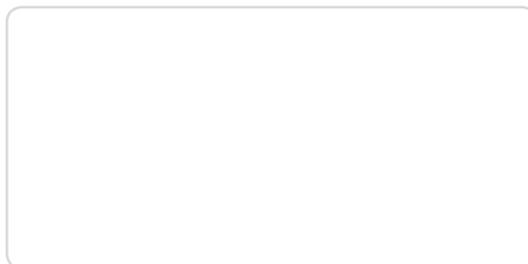
Ankle spanning configuration for distal tibial fracture associated with ankle joint instability



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Instructions for Use: See actual package insert for Instructions for Use.

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