

# **GALAXY UNYCO™ FEMUR AND KNEE BRIDGING**

## CONTENTS

---

<b>INTRODUCTION</b>	<b>1</b>
<b>MAIN FEATURES</b>	<b>2</b>
<b>EQUIPMENT REQUIRED</b>	<b>7</b>
<b>FEMORAL APPLICATION</b>	<b>9</b>
<b>UNI-CORTICAL SCREW INSERTION</b>	<b>10</b>
<b>KNEE APPLICATION</b>	<b>20</b>
<b>UNI-CORTICAL SCREW INSERTION IN FEMUR</b>	<b>21</b>
<b>UNI-CORTICAL SCREW INSERTION IN TIBIA</b>	<b>26</b>
<b>DAMAGE CONTROL</b>	<b>30</b>
<b>MRI SAFETY INFORMATION</b>	<b>32</b>

Operative Technique Contributing Surgeon:

T. Bégué, MD  
M. Manca, MD  
S. Nayagam, MD  
H.C. Pape, MD

## INTRODUCTION

Rapid skeletal stabilisation with external fixation is used for some severe high energy fractures, especially in patients with multiple injuries either from combat or mass-casualty scenarios<sup>1,2,3</sup>. 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. The management of high-energy fractures can be considered a challenge because of local soft tissue damage and the presence of associated injuries. In patients with multiple injuries, damage control surgery is associated with a significant risk of infection because of compromised soft-tissue and the potential need for lengthy stays in intensive care units<sup>1,3,4</sup>.

The Galaxy UNYCO™ System is composed of various clamps, rods and screws that can be used to stabilise fractures of the femur, tibia and ankle including knee bridging application. The Galaxy UNYCO™ Femur is part of this system and is conceived for temporary stabilization of femur fractures and specifically achieving excellent stability without the screws perforating the medullary canal.

### 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 cases of polytrauma and emergency situations, quick fracture stabilization procedures may influence lifesaving outcomes positively

#### 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 Fixation System, thereby enabling additional injuries of the lower limb to be stabilised and linked to the Galaxy 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

### Bibliography

1. Tikka S, Bostman O, Marttinen E, Makitie I. A retrospective analysis of 36 civilian gunshot fractures. *J Trauma*. 1996 Mar; 40(3 Suppl): S212-6.
2. Mathieu L, Bazile F, Barthélémy R, Duhamel P, Rigal S. Damage control orthopaedics in the context of battlefield injuries: The use of temporary external fixation on combat trauma soldiers. *Orthop Traumatol Surg Res*. 2011 Dec; 97(8):852-9.
3. Carroll EA, Koman LA. External fixation and temporary stabilization of femoral and tibial trauma. *J Surg Orthop Adv*. 2011 Spring; 20(1):74-81.
4. Parekh AA, Smith WR, Silva S, Agudelo JF, Williams AE, Hak D, Morgan SJ. Treatment of distal femur and proximal tibia fractures with external fixation followed by planned conversion to internal fixation. *J Trauma*. 2008 Mar; 64(3):736-9.

### INTENDED USE

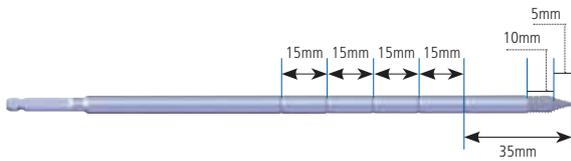
The Galaxy UNYCO™ system is intended to be used for temporary bone stabilization in trauma and orthopedic procedures of the lower limb prior to definitive treatment.

### INDICATIONS

Temporary stabilization of the femur, tibia\* and ankle\* in conditions and procedures, such as:

- Comminuted open or closed fractures
- 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 for bone-loss or other reconstructive procedures

\* For this application, please refer to the corresponding operative technique.

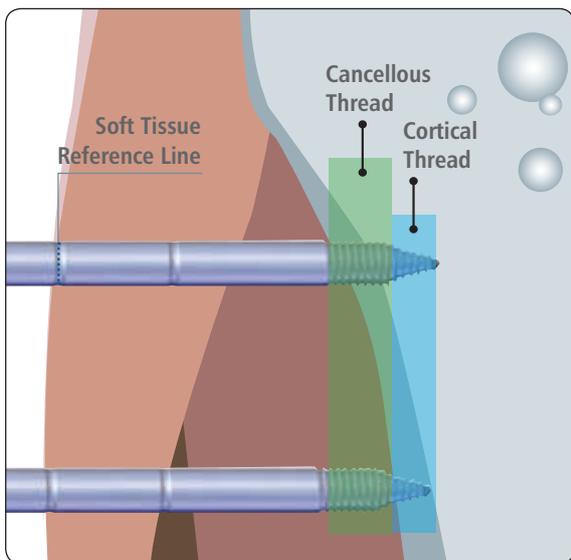
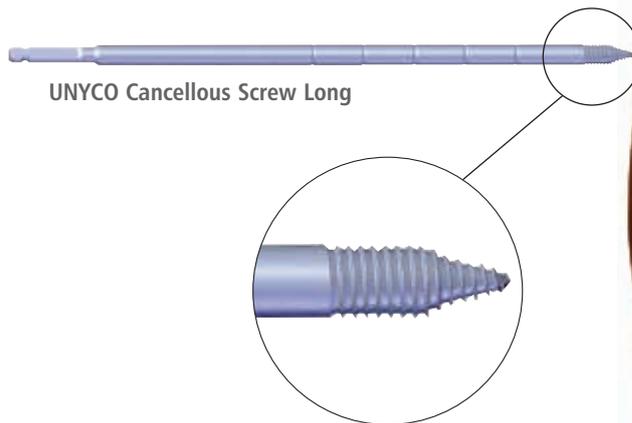


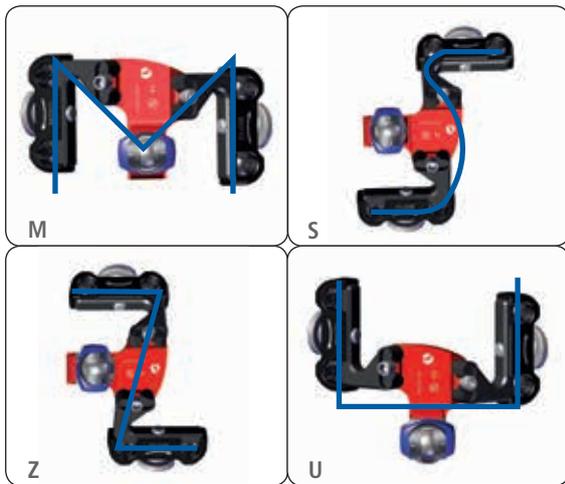
Part#	Description
93608	UNYCO Cancellous Screw Long QC Shaft Ø 6mm

## MAIN FEATURES

### UNYCO Cancellous Screw Long

The UNYCO Cancellous Screw Long is a uni-cortical screw designed for both diaphyseal and metaphyseal bone. The screw is made of surgical grade stainless steel, has a 6mm Ø shaft and its tip is conical. The conical thread is 5mm long, whereas the cylindrical thread is 10mm long (hence, the thread has a total length of 15mm). The special thread and tip design will enable screw insertion into the first cortex of the bone, avoiding perforation of the medullary canal. If the bone quality is insufficient, the surgeon can adjust the screw insertion depth by using the grooves as reference lines against the surface of the soft-tissues. The screw must never be backed out. The first groove is at 35mm from the screw tip, the other four grooves are at 15mm intervals.

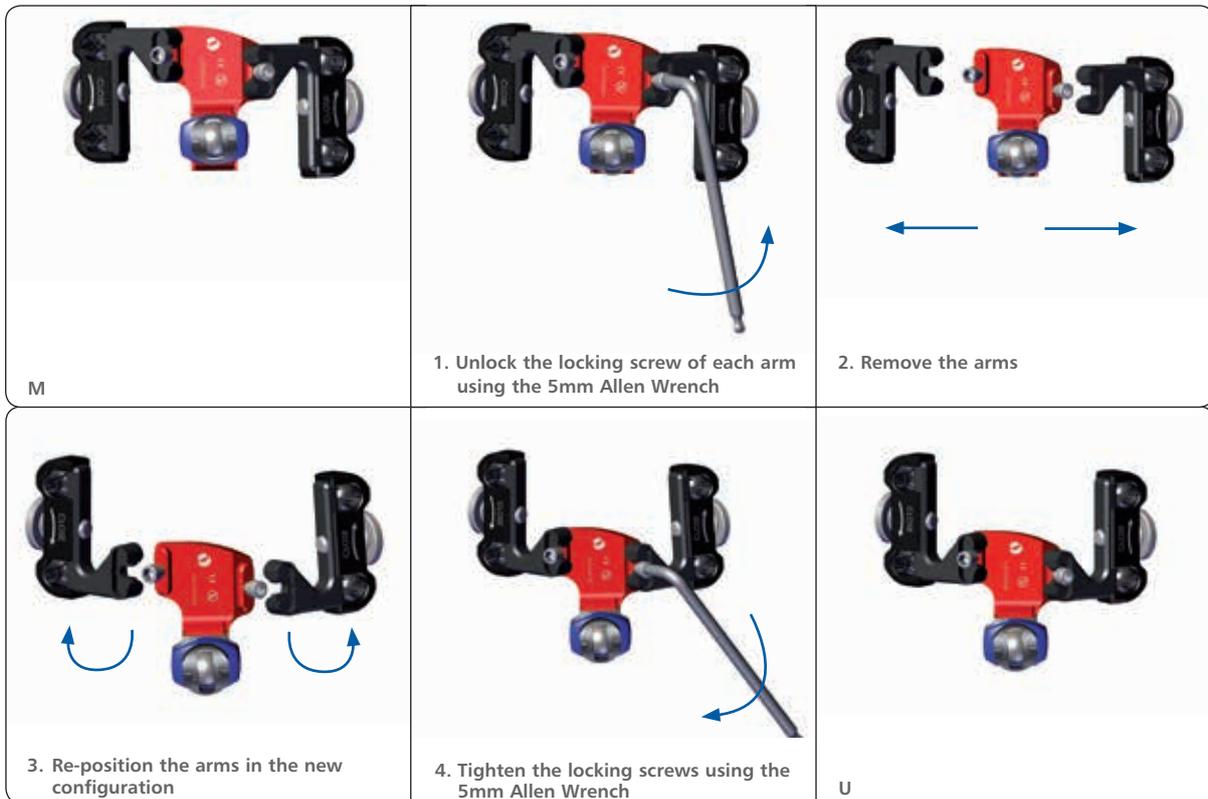




### Large Multiscrew Clamp for UNYCO Cancellous Screws Long

The Large Multiscrew Clamp for UNYCO Cancellous Screws Long (hereinafter "Femur Clamp") is provided in M configuration, but it can be easily converted to U, Z or S configurations by unlocking the arms with the universal Allen wrench and by re-positioning them (see below). This feature makes the system versatile.

#### How to change M to U configuration



#### From M to Z configuration



#### From M to S configuration

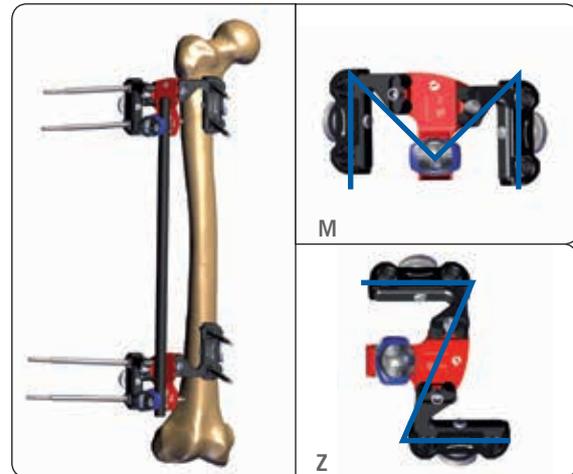


### Right femur configurations

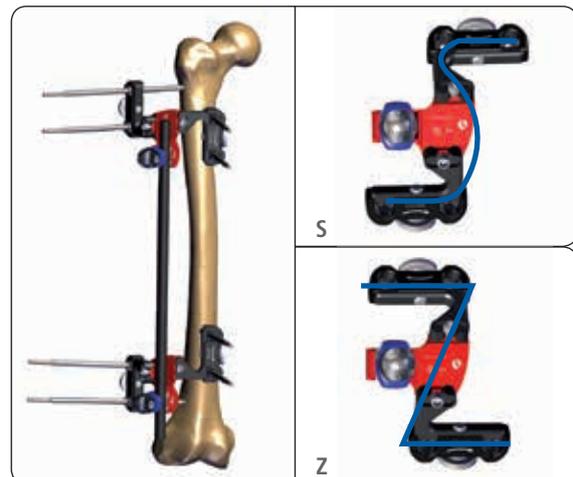
In the right femur, the Z configuration is suggested for the distal clamp to avoid perforating the suprapatellar pouch.

For the proximal clamp, the surgeon should choose the appropriate configuration based on patient and fracture characteristics.

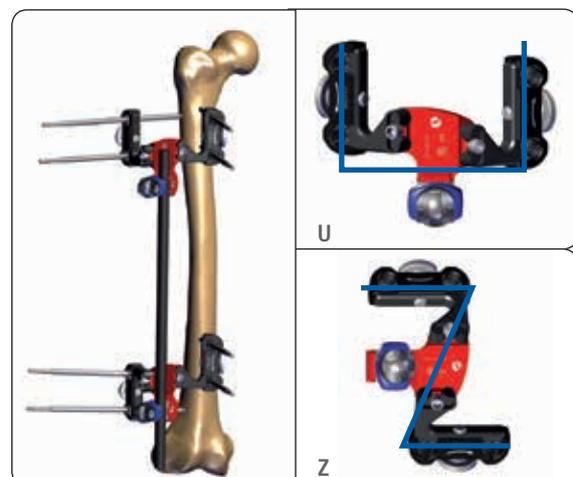
M-Z configuration



S-Z configuration



U-Z configuration



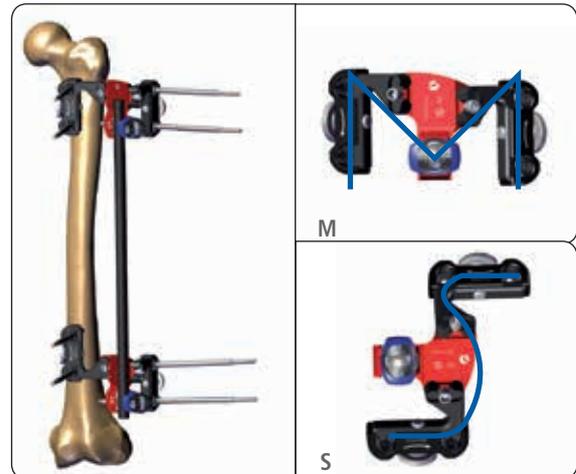
The U configuration might be used when definitive treatment with an antegrade nail is planned/foreseen. The compatibility between UNYCO and the chosen system must be verified prior to definitive treatment. Please see page 18 for more information.

## Left femur configurations

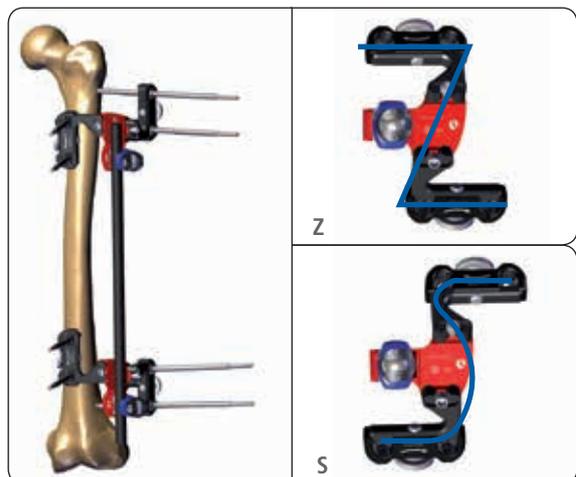
In the left femur, the S configuration is suggested for the distal clamp to avoid perforating the suprapatellar pouch.

For the proximal clamp, the surgeon should choose the appropriate configuration based on patient and fracture characteristics.

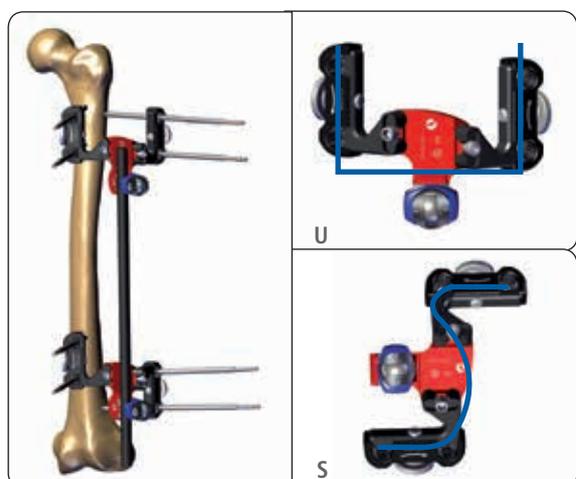
### M-S configuration



### Z-S configuration

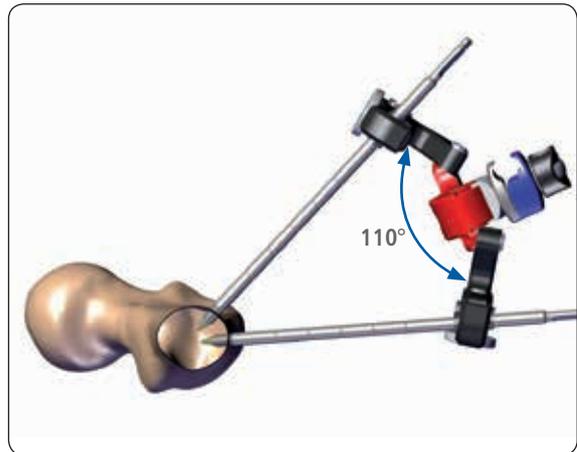


### U-S configuration



The U configuration might be used when definitive treatment with an antegrade nail is planned/foreseen. The compatibility between UNYCO and the chosen system must be verified prior to definitive treatment. Please see page 18 for more information.

The geometry of the Femur Clamp was studied and designed to optimise the adaptability to femoral anatomy. Thus, the two arms define an angle of  $110^\circ$  which facilitates screw insertion perpendicular to the bone surface.



The screw seats allow  $\pm 15^\circ$  variable angle screw positioning so that screws can be oriented independently.



## EQUIPMENT REQUIRED

Part#	Description	Qty
99-93790	Galaxy UNYCO Diaphyseal Femur Box	
can accommodate:		
99-93673	Galaxy UNYCO Mini Kit Femur Sterile	2
99-932400	Rod D12mm L 400 Sterile	1
99-93509	Mini Kit Instruments Sterile	1

Part#	Description	Qty
99-93791	Galaxy UNYCO Knee Bridging Box	
can accommodate:		
99-93673	Galaxy UNYCO Mini Kit Femur Sterile	1
99-93574	Galaxy UNYCO Mini Kit Tibia Sterile	1
99-932400	Rod D 12mm L 400mm Sterile	1
99-93509	Mini Kit Instruments Sterile	2



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

For manual screw insertion.



99-93673 - Galaxy UNYCO™ Mini Kit Femur Sterile



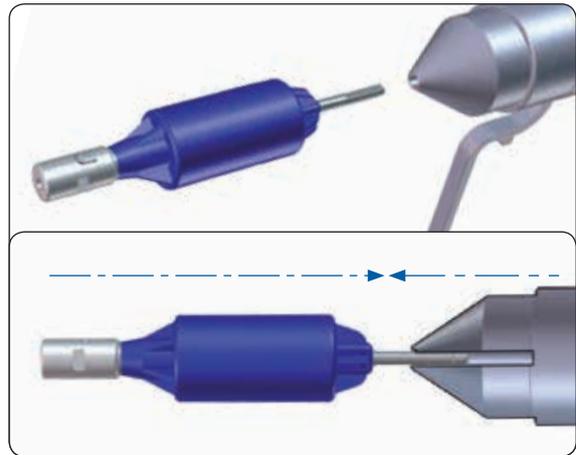
99-93574 - Galaxy UNYCO™ Mini Kit Tibia Sterile



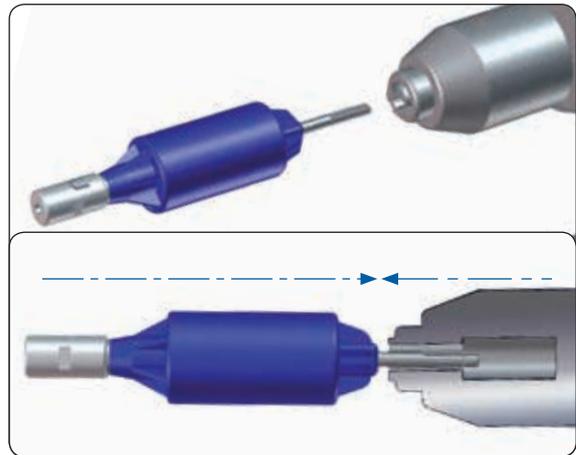
99-93509 - Mini Kit Instruments Sterile

### Power Drill Torque Limiter preparation

Assemble the Power Drill Torque Limiter (Ensure the axis is central within the drill and rotates concentrically).



With Quick Connection system



Without Quick Connection system  
(complete insertion into the cylindrical part)

Insert the UNYCO Cancellous Screw Long on the Power Drill Torque Limiter.



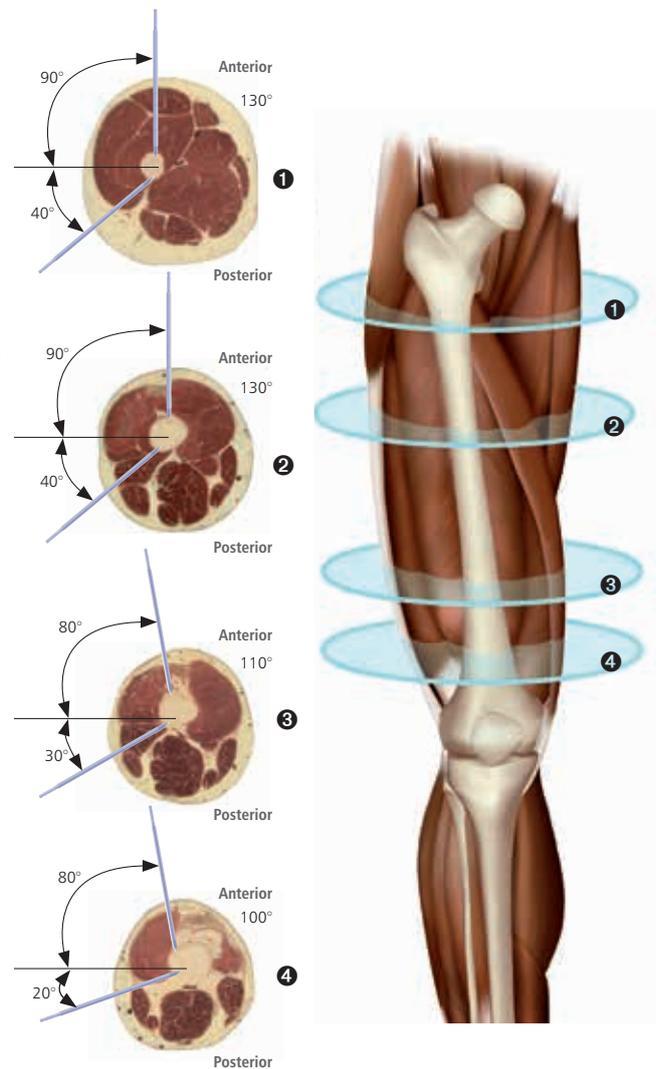
## FEMORAL APPLICATION

The Galaxy UNYCO™ System is composed of various clamps, rods and screws that can be used to stabilize fractures of the femur, tibia and ankle, including knee spanning application, prior to definitive treatment (as reported in the “Damage control” section).

The Galaxy UNYCO™ configurations, described in this manual and in the operative techniques for tibia and ankle applications, are assemblies suggested to achieve excellent stability through the optimal use of components and by efficient application. The rationale for choice of the screw position will depend on femoral anatomy at the chosen level of insertion.

In the femur, screws can be inserted within an arc of 90-80 degrees on the antero-lateral side and of 40-20 degrees on the postero-lateral side of the coronal plane. The size of this safe corridor will depend on the level in the femur (see adjacent image).

In damage control scenarios, the antero-lateral plane is recommended. This allows the supine position of the patient in bed and facilitates sufficient clearance to enable lateral submuscular plating of the femur or retrograde femoral intramedullary nailing to be accomplished, should this be the desired conversion to definitive stabilization.



### UNI-CORTICAL SCREW INSERTION

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

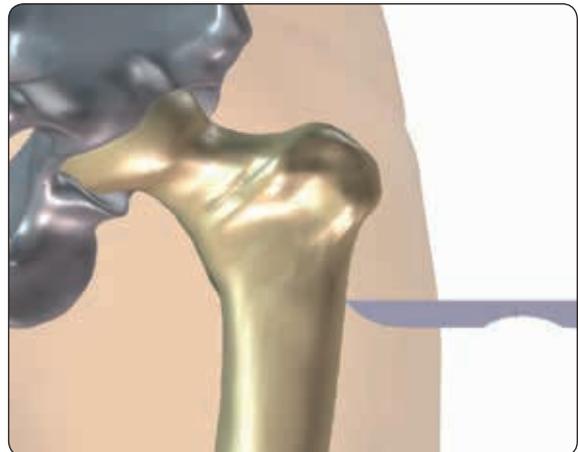


Fig. 1

Insert the first screw freehand, directly in the femur, without the clamp and starting from the most lateral screw (Fig. 2).

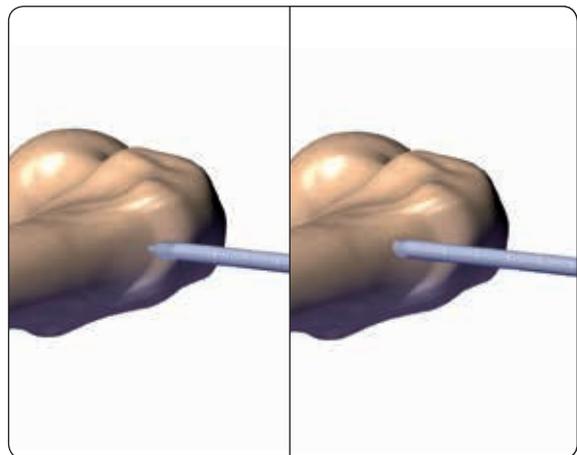


Fig. 2

**NOTE:** Check the correct position of the screw on the bone. Always attempt a perpendicular placement of the screw on the bone surface (Fig. 3).

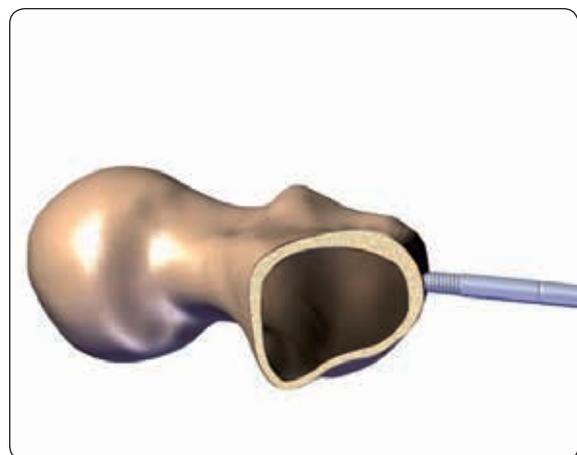


Fig. 3

### Screw Insertion

Drill the screw perpendicular to the bone surface (Fig. 4) using a low speed power drill with the Power Drill Torque Limiter (93568) already mounted. Alternatively, a limited torque wrench can be used.

The depth of penetration of the UNYCO Cancellous Screw Long in the cortex of diaphyseal bone is controlled by the torque limiter. The torque limiter decouples the drill when the required torque has been reached.

If the torque limiter does not decouple or if an insufficient quality of the bone is suspected, the surgeon should decide when to stop the drill by using the grooves as reference lines for penetration in the soft-tissues. An advance of the screw between each successive reference line is a distance of 15mm. The screw must never be backed out.

The depth of insertion of the UNYCO Cancellous Screw Long in the cancellous bone is controlled by the surgeon who decides when to stop the drill by using the reference lines against the surface of soft tissues as a guide for depth of penetration into bone. The screw must never be backed out.

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.

Apply the Femur Clamp (93666) on the first screw and provisionally tighten the metal ring on the arm clockwise by hand (Fig. 5).

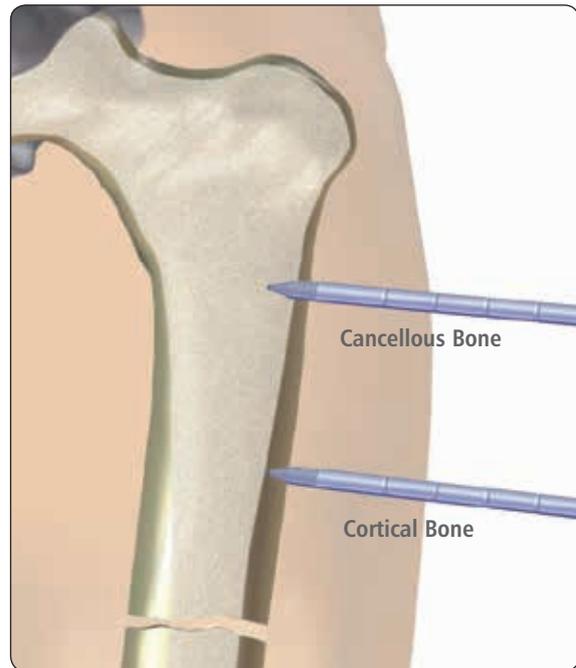


Fig. 4

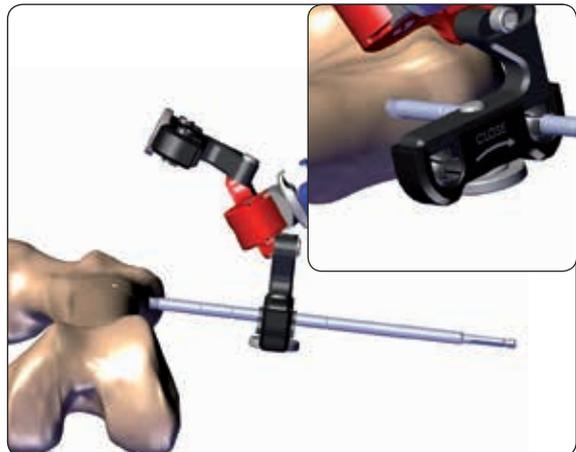


Fig. 5

**NOTE:** Once converging 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 40mm or approximately 2 fingers breadth) of the clamp from the skin before inserting the second screw. Please note that the distance of the clamp from the skin partially influences the position of the other screws in the bone segment.

**WARNING:** Stability of the clamp relies on correct spacing between the screws at the bone surface. To guarantee the system's stability, screws must be accurately inserted aiming at the center of the bone (Fig. 6a-b).

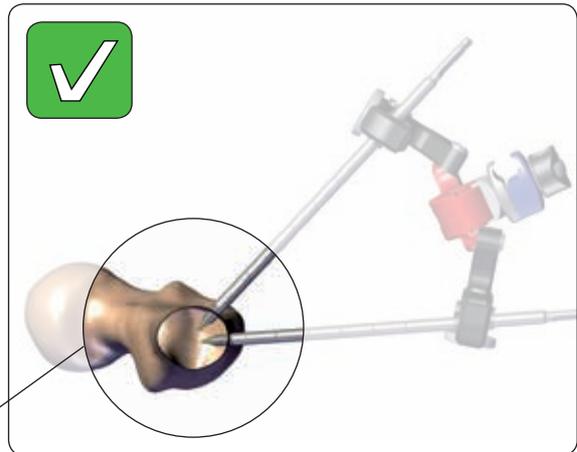


Fig. 6a

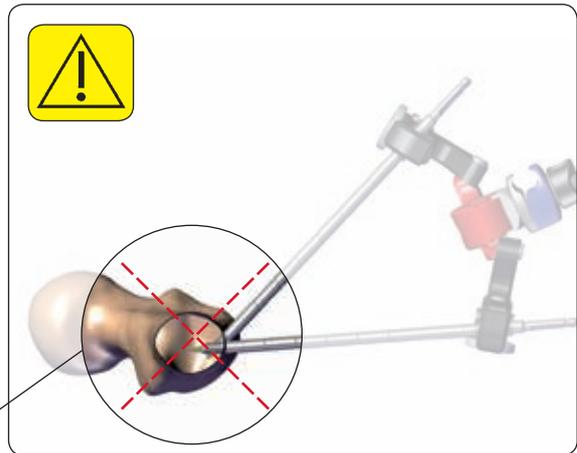
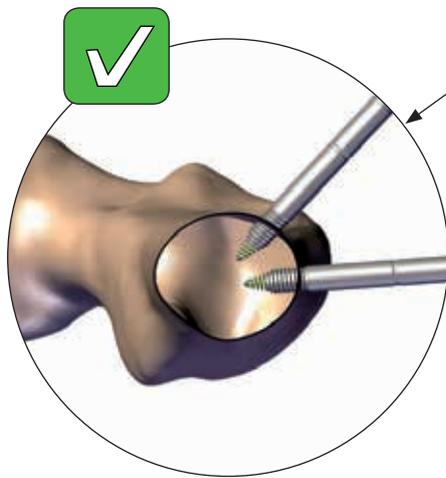
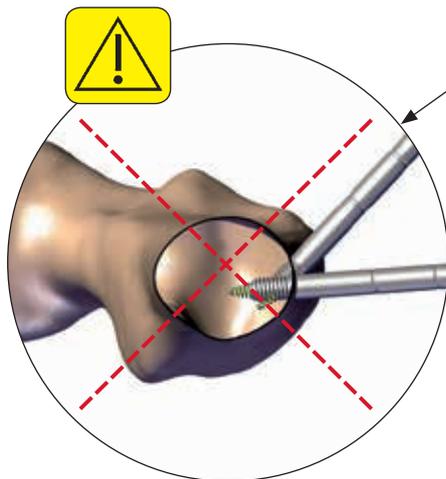


Fig. 6b



Using the Femur Clamp 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. 7).

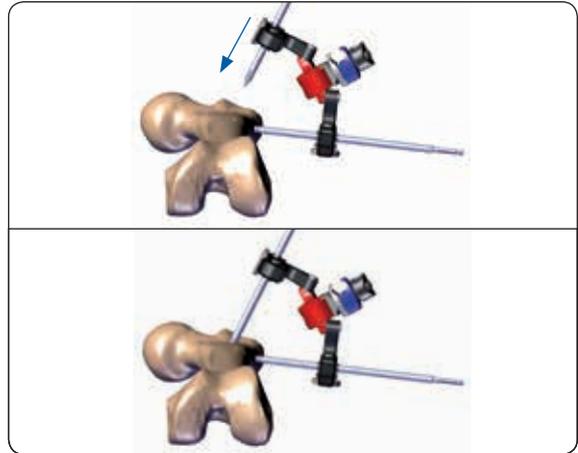


Fig. 7

The clamp should not be pulled/pushed after the second screw is inserted (Fig. 8).

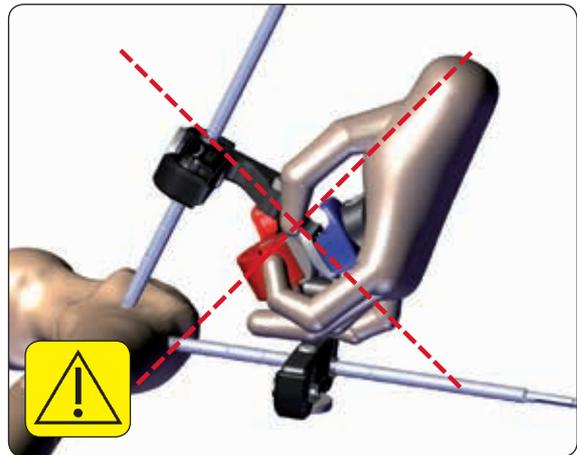


Fig. 8

Using the Femur Clamp as a template for screw insertion, insert the third and fourth screws in the corresponding arm, trying to be as perpendicular as possible to the bone surface (Fig. 9-10).

**WARNING:** The system stability is guaranteed only with 4 screws coupled with the Femur Clamp.

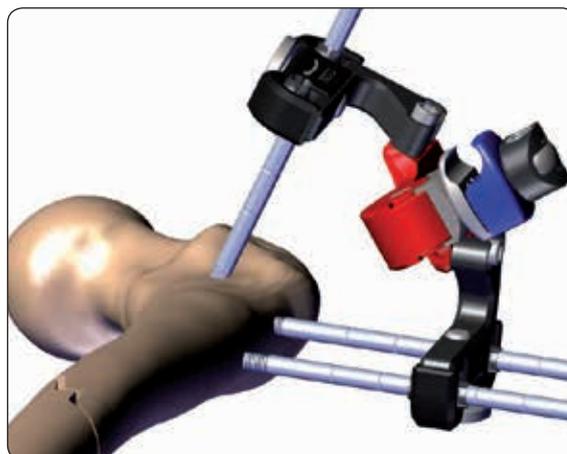


Fig. 9

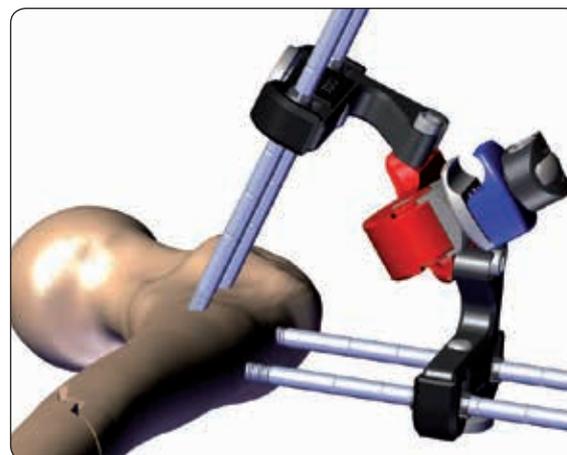


Fig. 10

Once all screws in each arm have been inserted, fully tighten both metal rings with the 5mm Allen Wrench (30017) (Fig. 11).

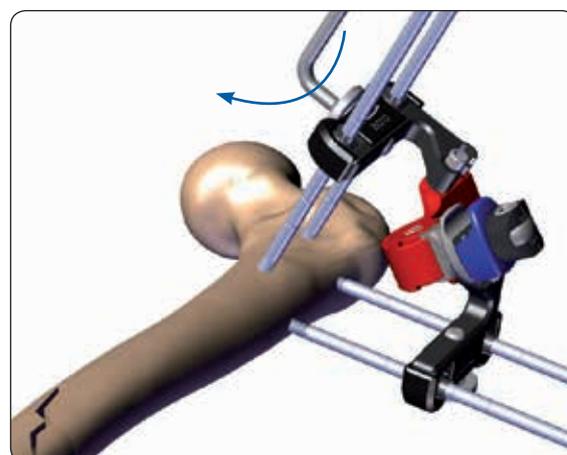


Fig. 11

A second Femur Clamp must be applied in the other bone segment by following the same steps described in the above "Screw Insertion" section (Fig. 12-13).

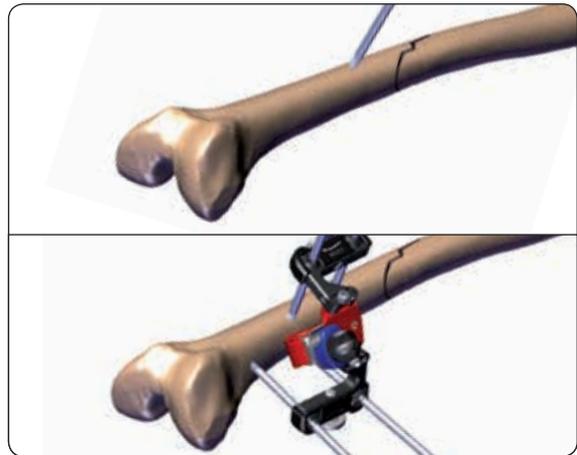


Fig. 12

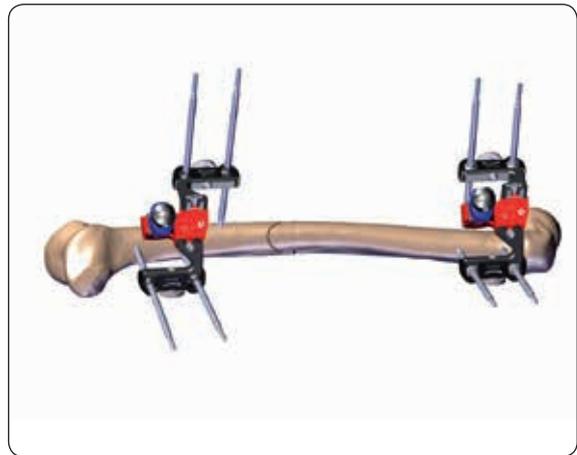


Fig. 13

Join both Femur Clamps with the rod leaving central rod clamp loosened to facilitate fracture reduction (Fig. 14).

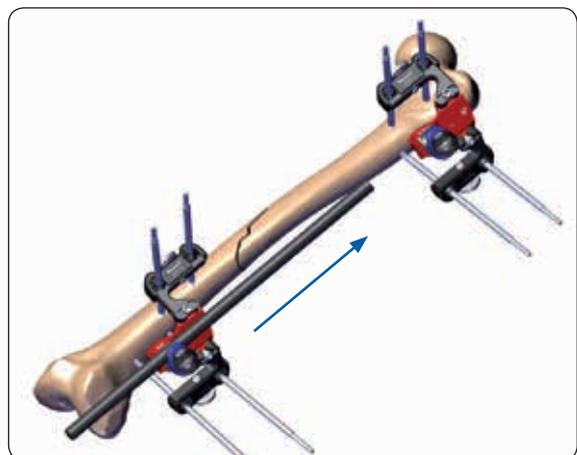


Fig. 14

Reduce the fracture, with X-ray guidance as necessary, holding the clamps to facilitate the reduction manoeuvre (Fig. 15).

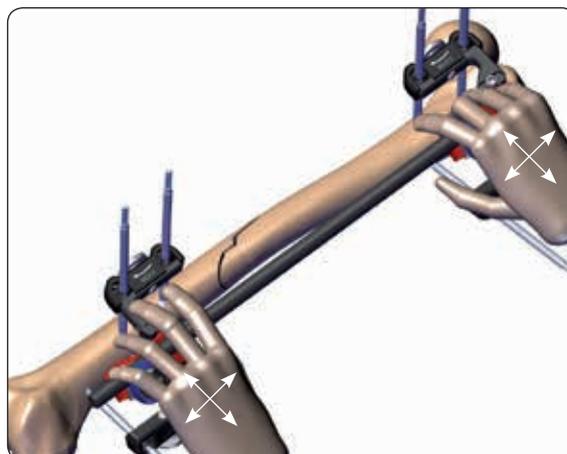


Fig. 15

Lock the clamps first manually by turning the knurled metal ring clockwise (Fig. 16).

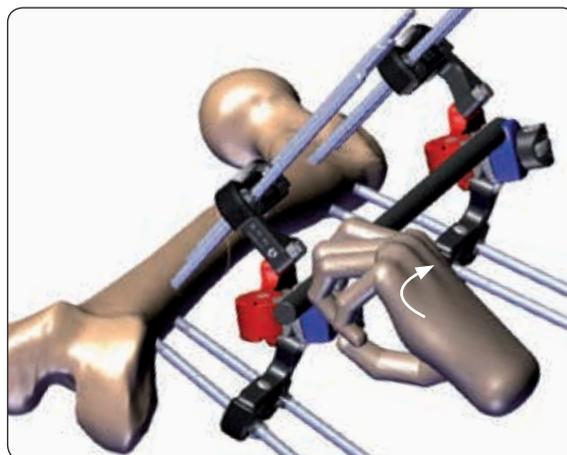


Fig. 16

If reduction is satisfactory, finally lock the rod clamps firmly by tightening the cams with the 5mm Allen Wrench (Fig. 17).

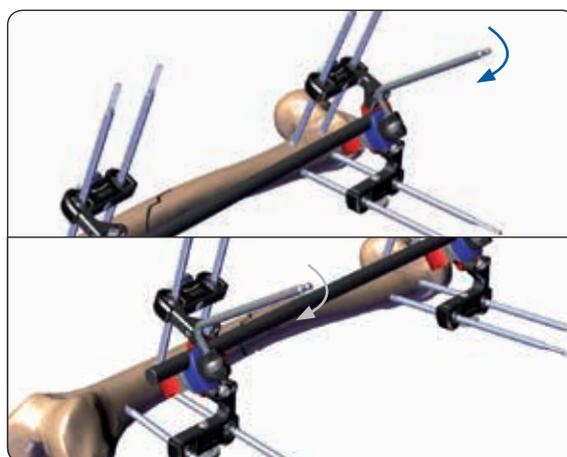


Fig. 17

In case of a segmental fracture, the middle segment can be stabilised using additional UNYCO Cancellous Screws Long on different planes in a Galaxy Large Single Clamp Sterile (99-93010) attached to the same connecting rod that links the two Femur Clamps.

Before drilling the UNYCO Cancellous Screw Long 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. 18).

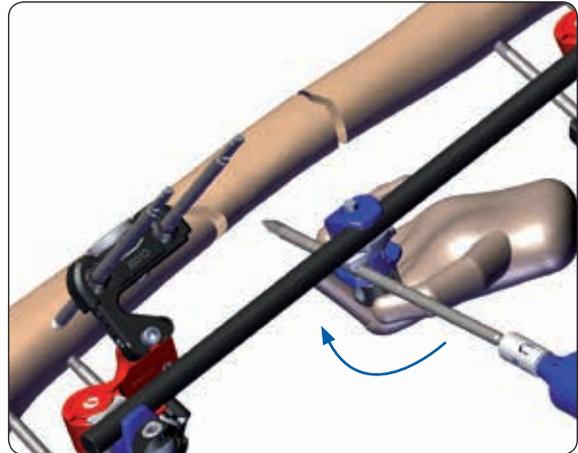


Fig. 18

Finally, lock the clamp with the Allen Wrench (Fig. 19).

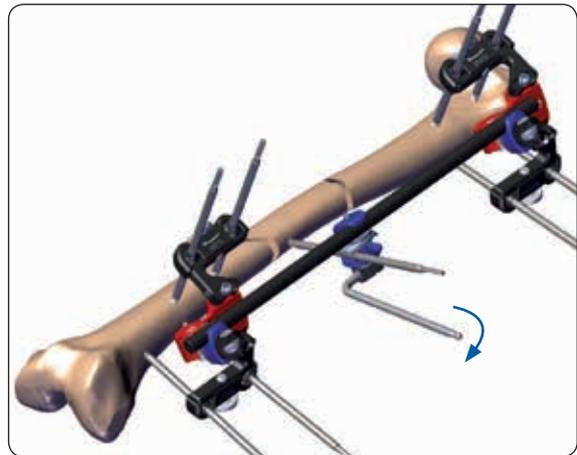


Fig. 19

Follow the same manoeuvre to insert an additional screw in the middle segment (Fig. 20).



Fig. 20

**CHANGING TO DEFINITIVE TREATMENT**

If intramedullary nailing of the fracture is envisaged as definitive treatment, it is usually not necessary to remove the fixator. Prior to conversion surgery, clean and brush the Galaxy UNYCO frame or cover the entire assembly with a sterile drape or similar to avoid contamination in the operative field.

If the system is perceived as an impediment for the correct definitive treatment application, remove the system parts where needed by applying the following manoeuvres.

Unlock the metal ring of the arm of the hindering Femur Clamp (Fig. 21).

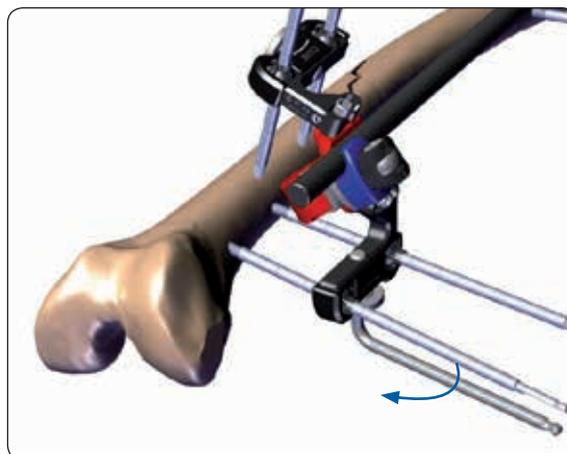


Fig. 21

Remove the uni-cortical screws (Fig. 22).

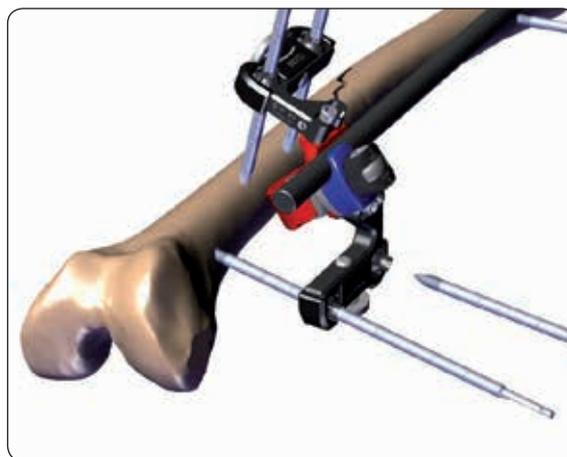


Fig. 22

Unlock the locking screw of the arm with the 5mm Allen Wrench (Fig. 23).

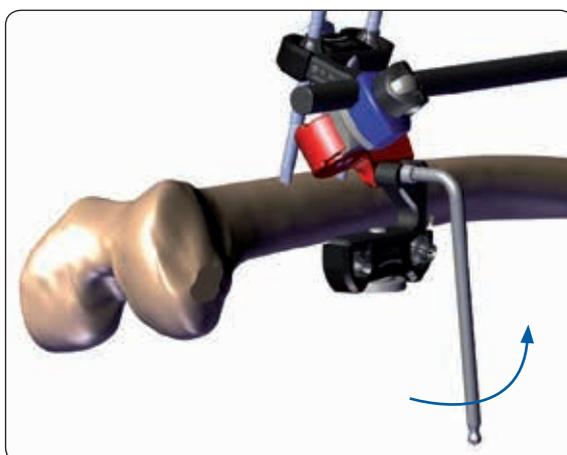


Fig. 23

Remove the arm (Fig. 24).



Fig. 24

If necessary repeat the procedure with the other clamp (Fig. 25).

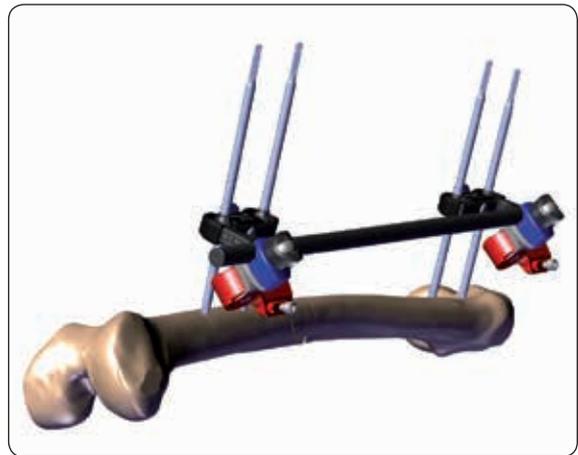


Fig. 25

**MAIN FEATURES**

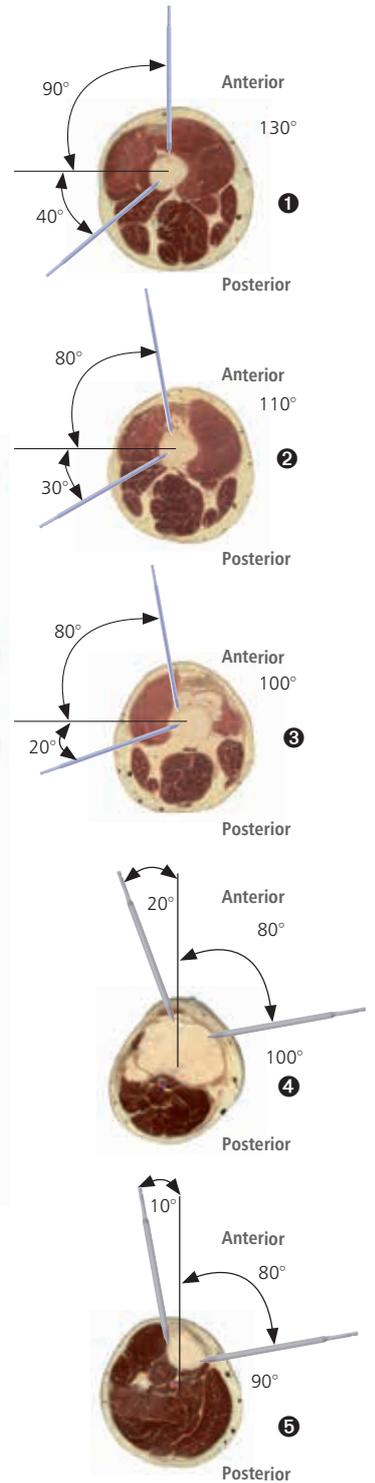
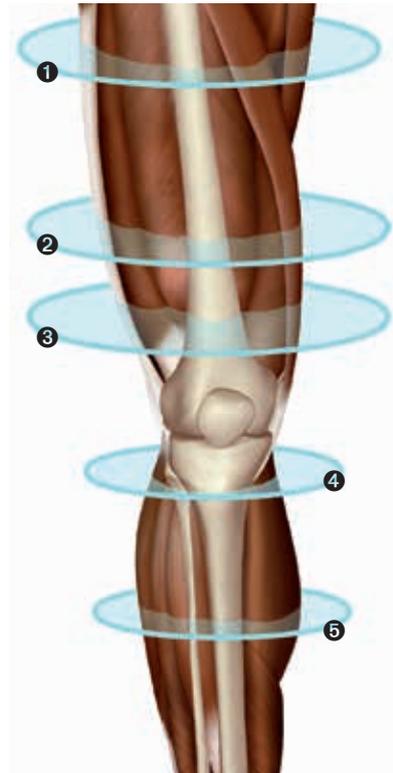
**KNEE APPLICATION**

In the femur and in the tibia, screws can be inserted within the safe corridors illustrated in the cross-sections.

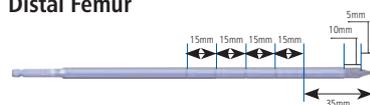
The size of these safe corridors will depend on the level in the femur and in the tibia (see adjacent images).

In damage control scenarios, in the femur the antero-lateral plane is recommended. This allows the supine position of the patient in bed and facilitates sufficient clearance to enable lateral submuscular plating of the femur or retrograde femoral intramedullary nailing to be accomplished, should this be the desired conversion to definitive stabilization.

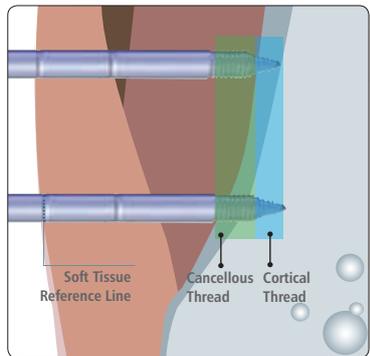
In the tibia, screws can be inserted within an arc of 10-20 degrees on the antero-lateral side and of 80 degrees on the postero-medial side of the coronal plane.



**Distal Femur**



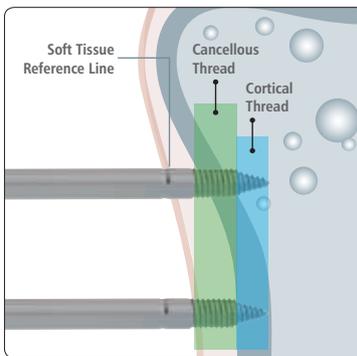
Part#	Description
93608	UNYCO Cancellous Screw Long QC Shaft Ø 6mm



**Proximal Tibia**



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



## UNI-CORTICAL SCREW INSERTION IN FEMUR

**NOTE:** for the equipment required see page 7.

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



Fig. 1

Insert the first screw freehand, directly in the femur, without the clamp and starting from the most lateral screw (Fig. 2).

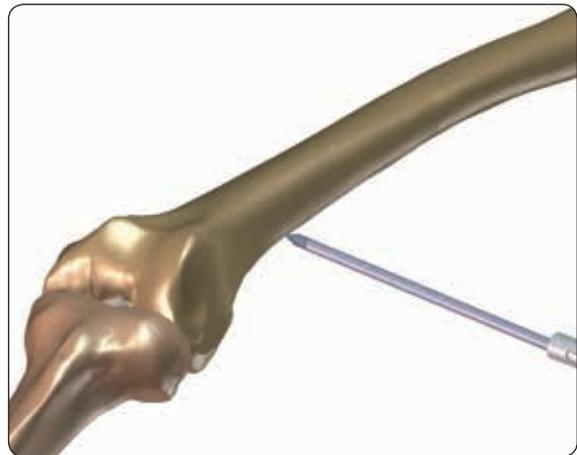


Fig. 2

**NOTE:** Check the correct position of the screw on the bone. Always attempt a perpendicular placement of the screw on the bone surface (Fig. 3).

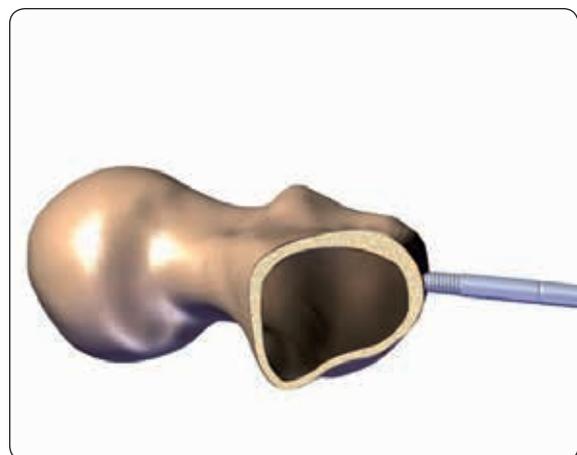


Fig. 3

### Screw Insertion

Drill the screw perpendicular to the bone surface (Fig. 4) using a low speed power drill with the Power Drill Torque Limiter (93568) already mounted. Alternatively, a limited torque wrench can be used.

The depth of penetration of the UNYCO Cancellous Screw Long in the cortex of diaphyseal bone is controlled by the torque limiter. The torque limiter decouples the drill when the required torque has been reached.

If the torque limiter does not decouple or if an insufficient quality of the bone is suspected, the surgeon should decide when to stop the drill by using the grooves as reference lines for penetration in the soft-tissues. An advance of the screw between each successive reference line is a distance of 15mm. The screw must never be backed out.

The depth of insertion of the UNYCO Cancellous Screw Long in the cancellous bone is controlled by the surgeon who decides when to stop the drill by using the reference lines against the surface of soft tissues as a guide for depth of penetration into bone. The screw must never be backed out.

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.

Apply the Femur Clamp (93666) on the first screw and provisionally tighten the metal ring on the arm clockwise by hand.

**NOTE:** If the UNYCO Cancellous Screws Long are applied close to the knee joint use the Large Multiscrew Clamp for UNYCO Cancellous Screws Long (hereinafter "Femur Clamp") in 'Z' configuration for the right femur and in 'S' configuration for the left femur (see pages 4-5). Otherwise, if the screws are applied more proximally, the surgeon can choose the most appropriate clamp configuration based on patient and fracture characteristics.

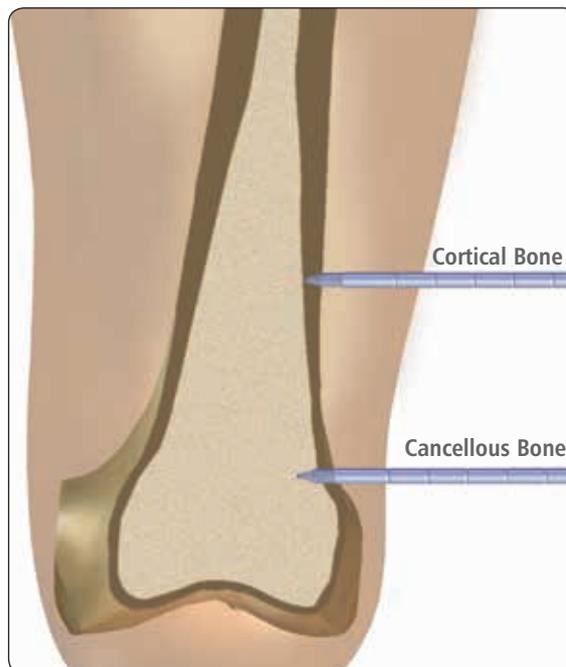


Fig. 4

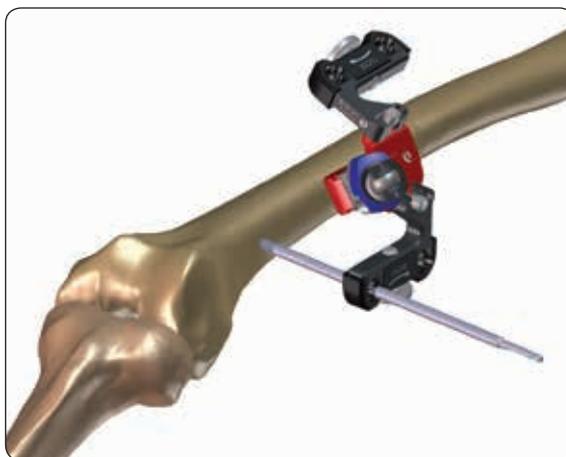


Fig. 5

Using the Femur Clamp 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. 6).



Fig. 6

The clamp should not be pulled/pushed after the second screw is inserted (Fig. 7).

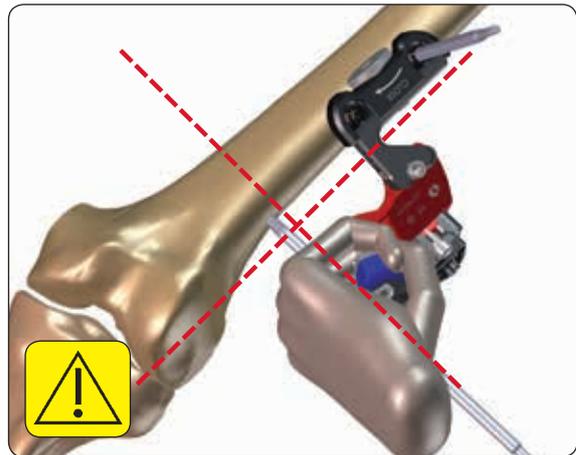


Fig. 7

**NOTE:** Once converging 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 40mm or approximately 2 fingers breadth) of the clamp from the skin before inserting the second screw. Please note that the distance of the clamp from the skin partially influences the position of the other screws in the bone segment.

**WARNING:** Stability of the clamp relies on correct spacing between the screws at the bone surface. To guarantee the system's stability, screws must be accurately inserted aiming at the center of the bone (Fig. 8a-b).

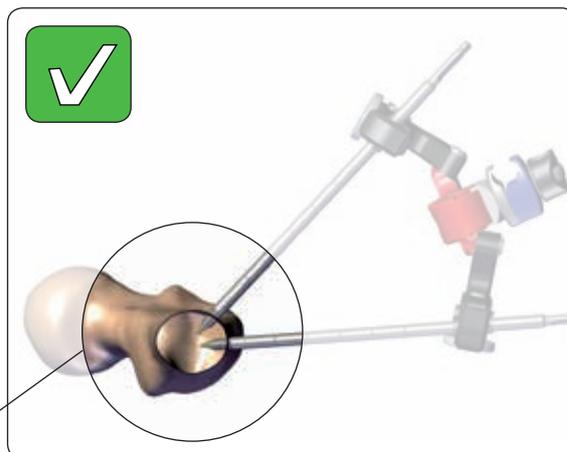


Fig. 8a

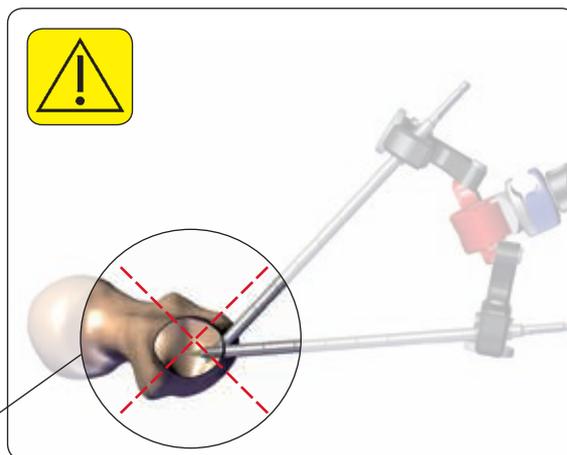
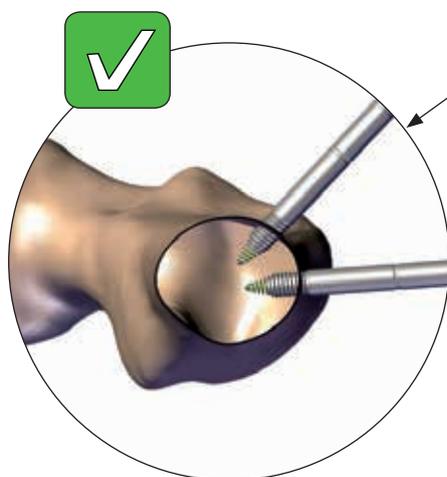
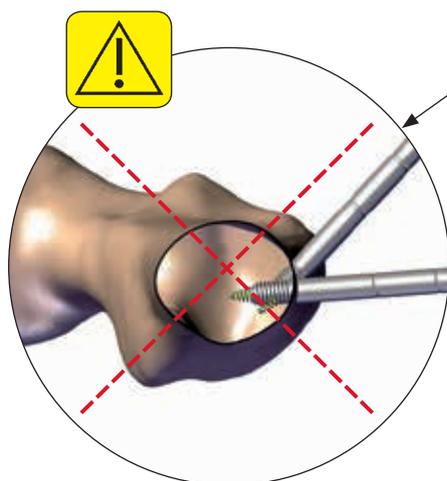


Fig. 8b



Using the Femur Clamp as a template for screw insertion, insert the third and fourth screws in the corresponding arm, trying to be as perpendicular as possible to the bone surface (Fig. 9-10).

**WARNING:** The system stability is guaranteed only with 4 screws coupled with the Femur Clamp.



Fig. 9



Fig. 10

Once all screws in each arm have been inserted, fully tighten both metal rings with the 5mm Allen Wrench (30017) (Fig. 11).

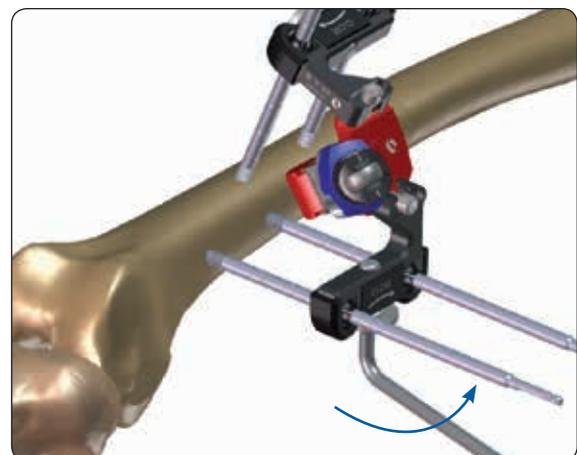


Fig. 11

## UNI-CORTICAL SCREW INSERTION IN TIBIA

Make a 5mm puncture in the skin at the insertion site of the first antero-lateral screw (Fig. 12).



Fig. 12

Insert the first UNYCO Cancellous Screw freehand, without the clamp, directly over the lateral tibial crest (Fig. 13) to it and check its correct position on the bone.

**NOTE:** Always attempt a perpendicular placement of the screw on the bone surface.

### 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.

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. 13

Apply the Large Multiscrew Clamp for UNYCO Cancellous Screws (hereinafter "Tibia Clamp") (93566) on the first screw and tighten the metal ring on the arm clockwise (Fig. 14).

**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. 14).

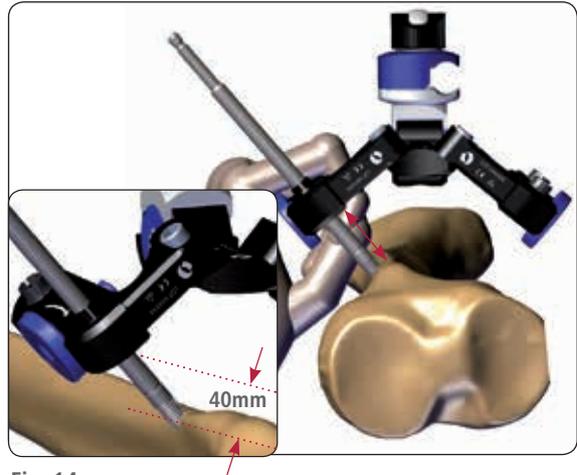


Fig. 14

Using the Large Tibia 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. 15).

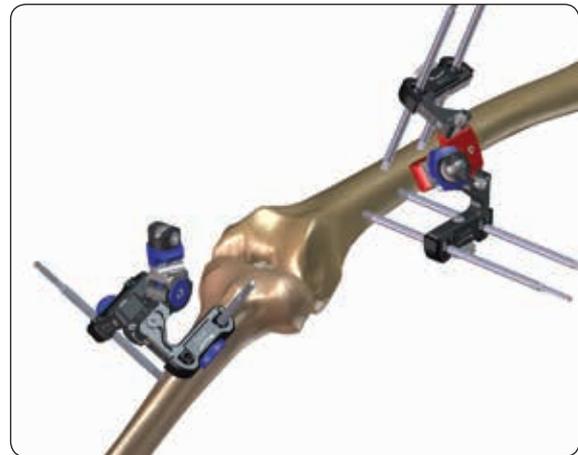


Fig. 15

The clamp should not be pulled/pushed after the second screw is inserted (Fig. 16).

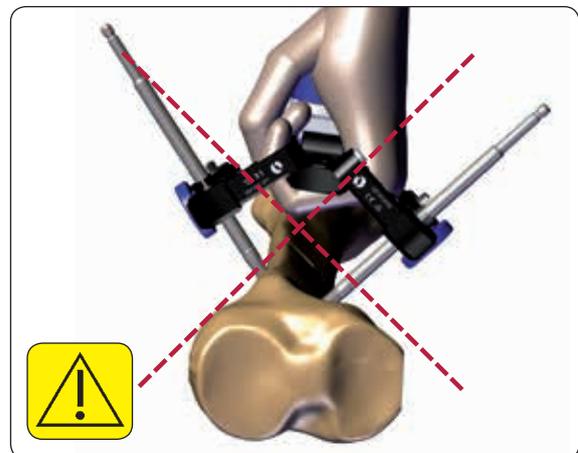


Fig. 16

**WARNING:** On the tibia, the system stability is guaranteed only with 4 screws coupled with the Large Tibia Clamp in each bone segment (Fig. 17).

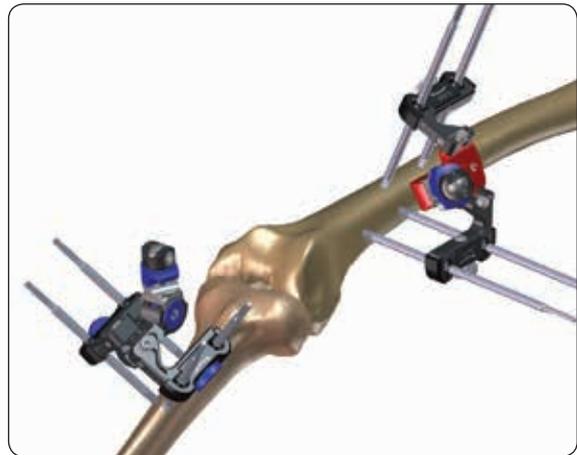


Fig. 17

Once all screws in each arm have been inserted, tighten both metal rings fully with the 5mm Allen Wrench (30017) (Fig. 18).

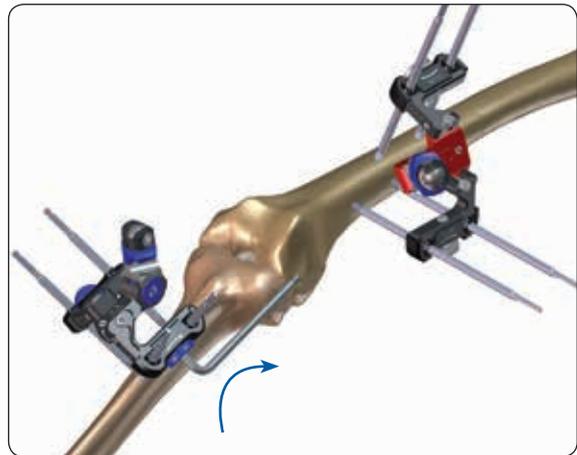


Fig. 18

#### CONNECTION OF THE LARGE MULTISCREW CLAMPS

Connect the Large Multiscrew Clamps with a 12mm Galaxy rod (Fig. 19).

Leave the rod clamps loosened and achieve reduction or suitable positioning of the knee joint by maneuvering the clamps. Use X ray guidance as needed.

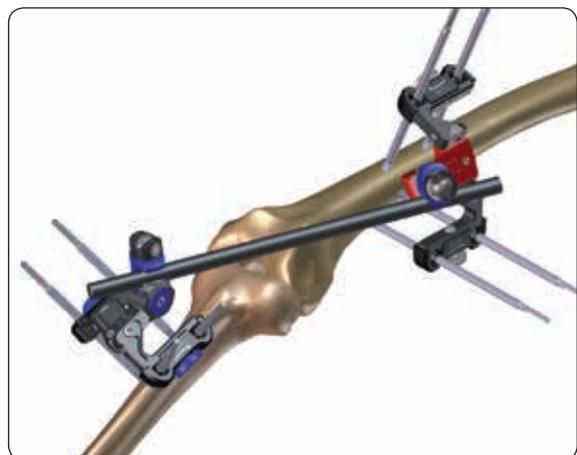


Fig. 19

Then, lock the rod clamps firmly by tightening the cams with the 5mm Allen Wrench (Fig. 20).

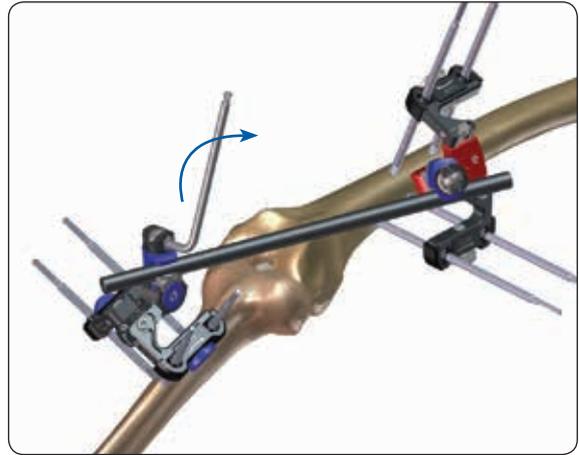


Fig. 20

#### USE OF ADDITIONAL GALAXY FIXATION COMPONENTS

When the Large Multiscrew Clamps are applied in the proximal femur and in the distal tibia additional Galaxy Fixation component will be needed. Two rods are connected to each other by using a Large Single Clamp Sterile (99-93010). On the basis of patient and fracture characteristics additional Galaxy Fixation rods and clamps can be added to the construct to increase stability (Fig. 21).

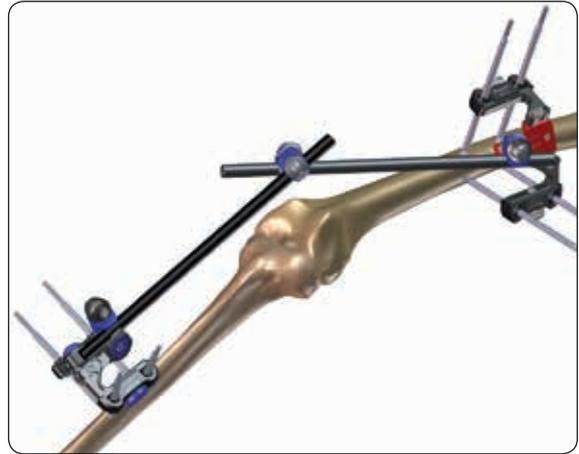
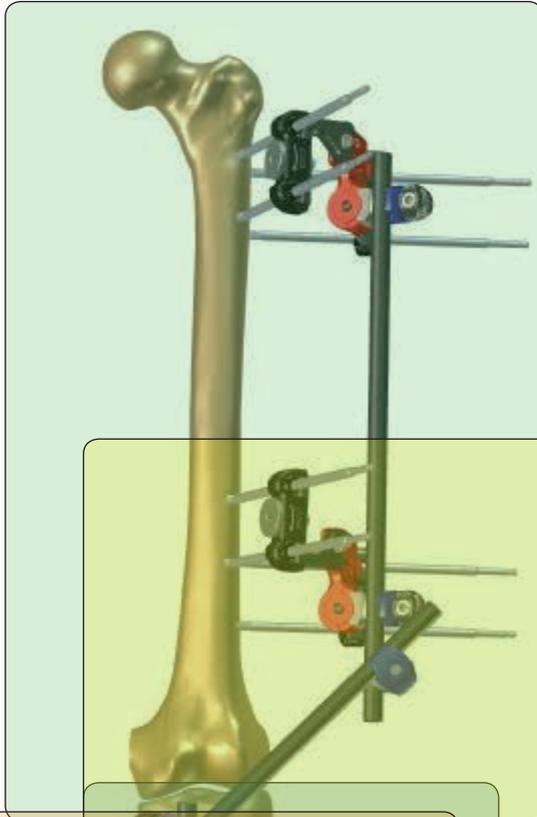


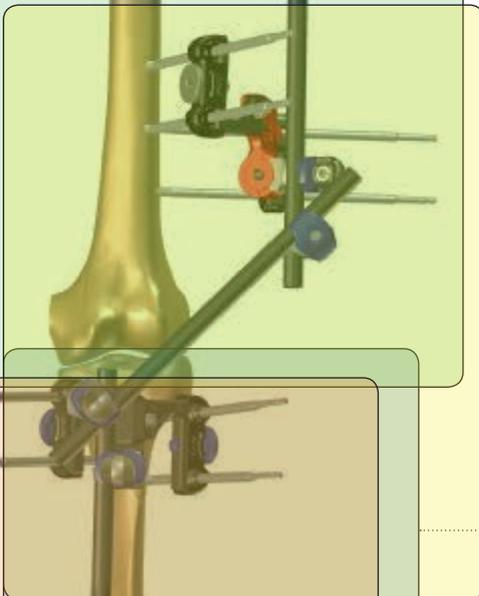
Fig. 21

**DAMAGE CONTROL**

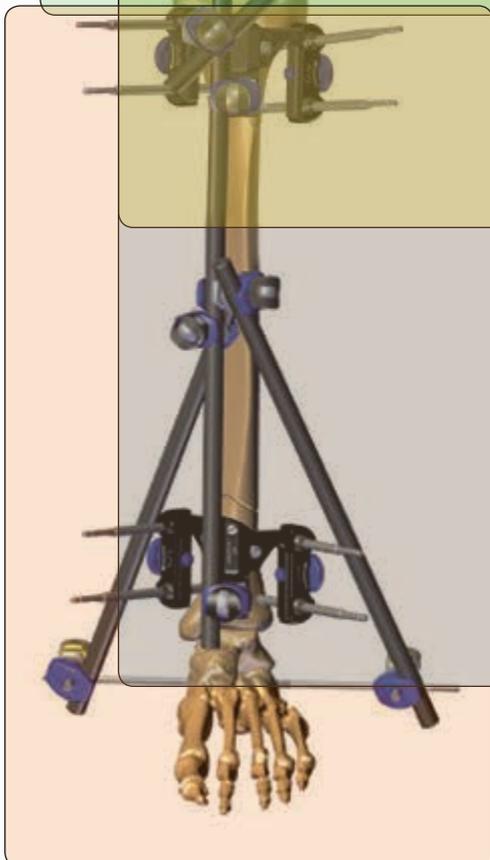


The Galaxy UNYCO System is composed of various clamps, rods and screws that can be used to stabilise fractures of the femur, tibia and ankle including knee bridging application.

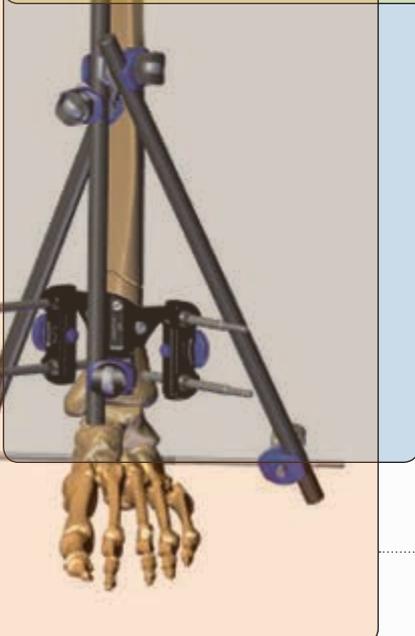
**Femur application for diaphyseal fractures  
(including segmental fractures)**



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



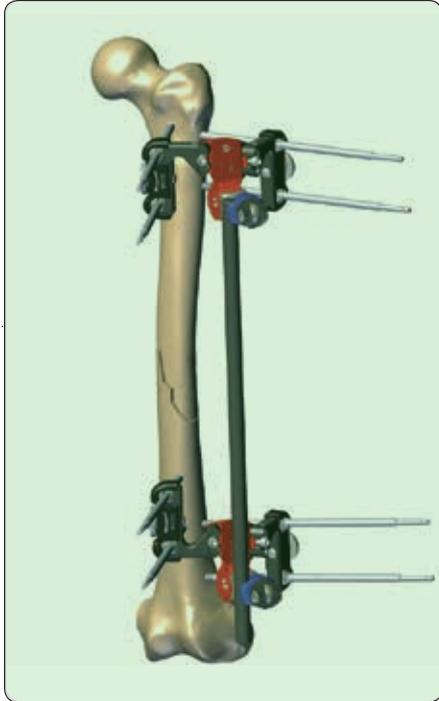
**Tibial application for diaphyseal fractures  
(including segmental fractures)**



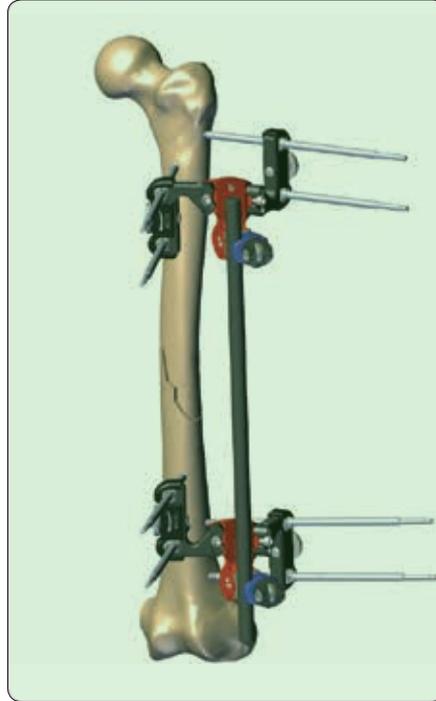
**Ankle bridging configuration for peri-articular fractures  
or ligamentous injuries**

Standard configurations for left femoral diaphyseal fractures  
(including segmental fractures)

M - S



Z - S



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



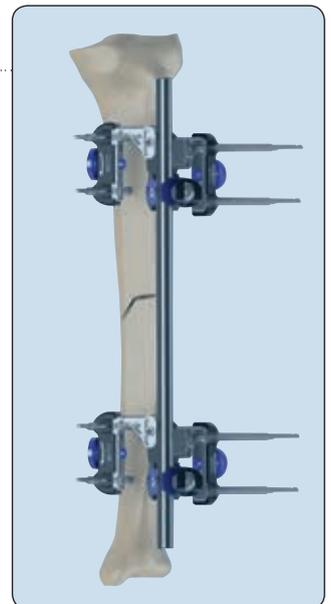
UNILATERAL FRAME



DELTA FRAME



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



## MRI SAFETY INFORMATION

Galaxy UNYCO™ System is labeled MR CONDITIONAL  according to the terminology specified in "ASTM F2503 Standard Practice for Marking Medical Devices and Other Items in the Magnetic Resonance Environment".

**Note:** All components of Galaxy UNYCO™ System must be identified as MR Conditional prior to being placed in or near an MR Environment.

Non-clinical testing has demonstrated that the Galaxy UNYCO™ System components are MR Conditional. It can be safely scanned under the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial magnetic field gradient of 900-Gauss/cm (90 mT/cm).
- Maximum whole-body-averaged specific absorption rate (SAR) of  $\leq 4.0$  W/kg (First Level Controlled Operating Mode).
- No local transmit/receive coils must be used on the device.
- The Galaxy UNYCO™ System components must be entirely outside the MR scanner bore.
- No part of the Galaxy UNYCO™ System components must extend into the MR bore. Therefore MR scanning of body parts where the Galaxy UNYCO™ System components are located is contraindicated.

### DISPLACEMENT INFORMATION

The system will not present an additional risk or hazard to a patient in the 1.5 and 3.0 Tesla MR environment with regard to translational attraction or migration and torque.

### HEATING INFORMATION

Under the scan conditions defined above, the Galaxy UNYCO™ System is expected to produce a maximum temperature rise of 2°C after 15 minutes of continuous scanning.

### PATIENT SAFETY

MRI in patients with Galaxy UNYCO™ System components can only be performed under these parameters. It is not allowed to scan the Galaxy UNYCO™ System components directly. Using other parameters, MRI could result in serious injury to the patient. When the Galaxy UNYCO™ System components are 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 UNYCO™ System can only be guaranteed for MRI when using the following components to build the frames:

#### Tibia frame

---

2 x Large Multiscrew Clamps for UNYCO Screws

---

1 x Rod Ø 12 mm L 350 mm

---

*Up to 8 within these screws available in the kit:*

---

8 x UNYCO Screw QC Shaft Ø 6 mm

---

4 x UNYCO Cancellous Screw QC Shaft Ø 6 mm

---

#### Ankle bridging - Delta frame

---

1 x Large Multiscrew Clamps for UNYCO Screws

---

1 x Transfixing Pin Thread L80mm Shaft Ø 4mm,  
Thread Ø 5mm

---

2 x Rod Ø 12mm L 350mm

---

4 x UNYCO Cancellous Screw QC Shaft Ø 6mm

---

1 x Galaxy Large Clamp

---

2 x Galaxy Large-Medium Transition Clamp

---

#### Ankle bridging - Unilateral frame

---

1 x Large Multiscrew Clamps for UNYCO Screws

---

1 x Radiolucent Foot Unit

---

2 x Rod Ø 12mm L 350mm

---

7 x UNYCO Cancellous Screw QC Shaft Ø 6mm

---

6 x Galaxy Large Clamp

---

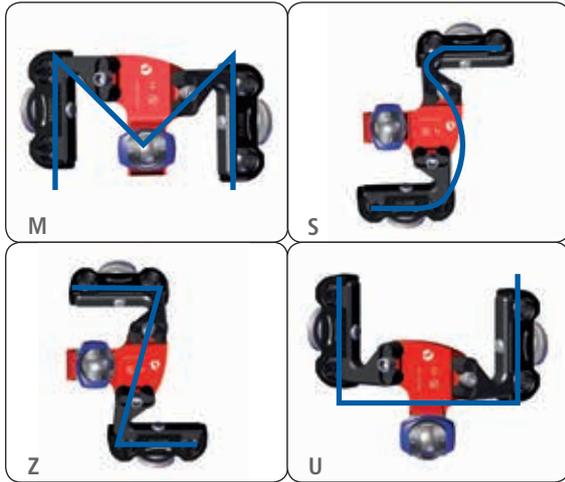
**Femur frame**

2 x Large Multiscrew Clamps For UNYCO Screws Long

8 x UNYCO Cancellous Screws Long QC Shaft Ø 6mm

1 x Rod Ø 12mm L 400mm Sterile

Tested clamp configurations: M+Z, U+Z, M+S, and U+S as illustrated below



**Knee bridging - frame**

1 x Large Multiscrew Clamp For UNYCO Screws Long in M or U or S or Z configuration

4 x UNYCO Cancellous Screws Long QC Shaft Ø 6mm

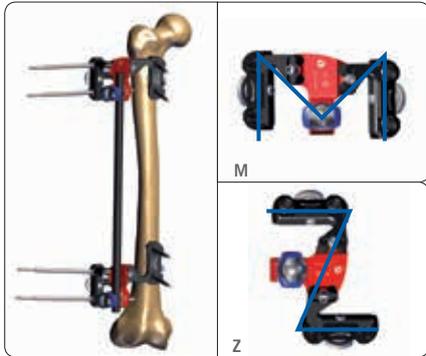
1 x Large Multiscrew Clamp For UNYCO Screws in M or U configuration

4 x UNYCO Cancellous Screw QC Shaft Ø 6mm

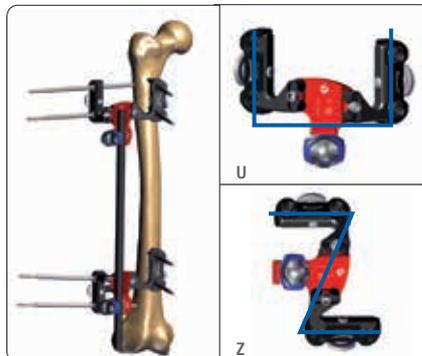
1 x Rod Ø 12mm L 400mm Sterile

**Right femur configurations**

**M-Z configuration**

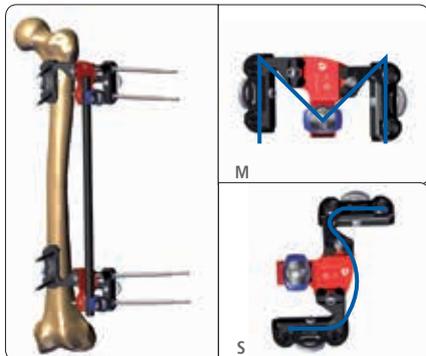


**U-Z configuration**

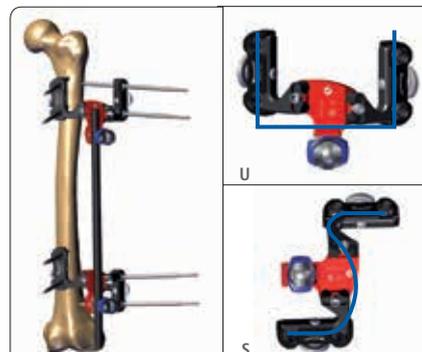


**Left femur configurations**

**M-S configuration**



**U-S configuration**

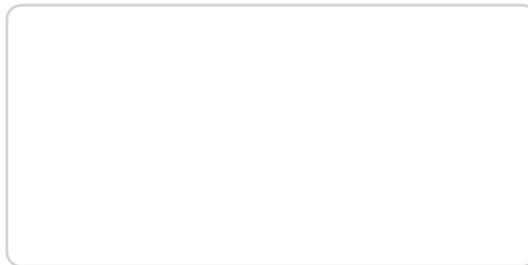




Manufactured by:  
ORTHOFIX Srl  
Via Delle Nazioni 9, 37012 Bussolengo (Verona), Italy  
Telephone +39 045 6719000, Fax +39 045 6719380



**Distributed by:**



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

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. 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.

[www.orthofix.com](http://www.orthofix.com)  
[www.galaxyunco.com](http://www.galaxyunco.com)

MC-1601-OPT-E0 C 09/17

