UNYCO GALAXY

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1. INTRODUCTION

For the treatment of severe high-energy open tibial fractures, especially of polytrauma patients and in disaster or combat situations, it is preferable to follow the principles of Damage Control Orthopedics and therefore surgeons generally perform a staged protocol consisting in temporary external fixation followed by definitive internal or external fixation [1, 2]. In this context, temporary external fixation is used as emergency procedure, therefore it must be fast, ensure good stabilization and provide versatility in application.
Tibia fractures that involve a severe injury to soft tissue can present several problems due to contamination, loss of soft-tissue support, and disruption of the periosteal blood supply [3, 4, 5]. Therefore, these fractures are associated with high rates of complications, such as deep infection [5, 6, 7].
For all these reasons, management of open tibial fractures remains a challenge for orthopaedic, plastic and vascular surgeons [7].

The Galaxy UNYCO has been designed to temporary stabilization of tibia fractures, without the need of entering with screws into the medullary canal.
The technical aspects of the components and the whole system are here presented, thus demonstrating the unique advantages and benefits that this system offers.

2. SYSTEM COMPONENTS: DESCRIPTION AND TECHNICAL FEATURES

The Galaxy UNYCO is a modular system composed of:

- Large multiscrew clamps
- Two UNYCO Screw types: UNYCO Screws and UNYCO Cancellous Screws
- 12mm Ø rod
- Power Drill Torque Limiter

The Galaxy UNYCO Diaphyseal Tibia Sterile Kit is intended to be used to provide bone stabilization in trauma, specifically lower limb fractures, that require temporary fixation prior to
definitive treatment.

The indications for use include:
- Tibial fractures extending from about 8cm below the knee to about 7cm above the ankle joint, including comminuted open or closed tibial fractures and polytrauma
- Temporary stabilization of the tibia after debridement for osteomyelitis or an infected nonunion pending second stage treatment.

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

The Galaxy UNYCO Diaphyseal Tibia Sterile Kit permits multiple frame configurations:

- Non-bridging configurations applied only on the tibia
- Knee and ankle spanning configurations in conjunction with Galaxy Fixation components

2.1 LARGE MULTISCREW CLAMP FOR UNYCO SCREWS

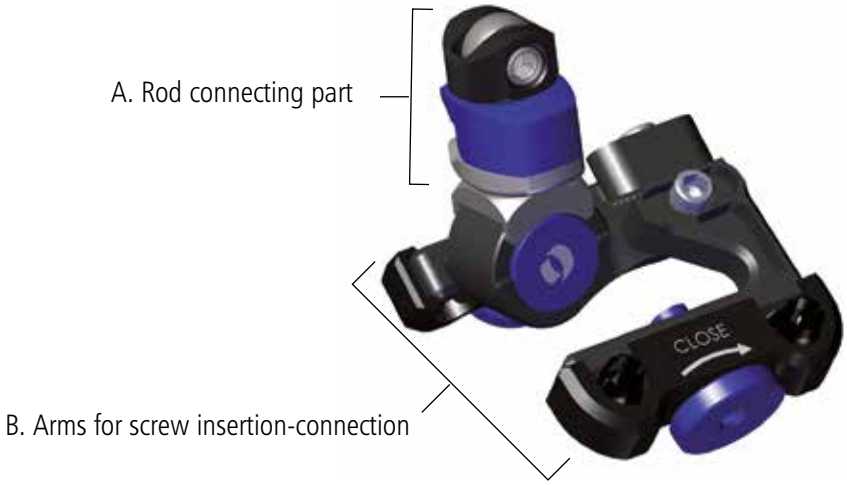


Fig. 1: Large Multiscrew Clamp for UNYCO Screws details

The Large Multiscrew Clamp for UNYCO Screws (Fig. 1) is composed of two parts:

A. Rod connecting part

The rod slot accommodates a 12mm Ø Galaxy rod and the snap in feature permits rapid connection and fast frame assembly. The particular geometry of the slots provides high torsional strength (internal reports). This helps to prevent rod sliding and gives high stability to the system.
Locking of the rod is done by tightening the cam: pre-closure can be performed manually and definitive closure by the universal Allen wrench.

B. The arms for screw insertion-connection

The clamp is composed of two arms for screw insertion-connection. The arms are "asymmetrical" as they are positioned on the clamp with a 8mm offset between them (Fig. 2).

Fig. 2: Arms are positioned on the clamp with a 8mm offset between them.

Each arm has two screws seats with a sphere which permits independent orientation of the screws the screws at variable angulation up to ±10° (Fig. 3).

Fig. 3: Screws can be inserted at variable angulation up to ±10°

The interaxis distance between the two screw seats in one arm is 40mm, which corresponds to the distance between screw seat 1 and 5 of the standard Orthofix clamps (e.g. ProCallus, LRS ADV, etc). This specific interaxis ensures proper system stability even if screws are inserted very convergent.
Pre-closure can be performed manually by using the locking screw knurled knob. This is positioned perpendicularly to the axis of the screws to facilitate closure and to make the system ergonomic. Definitive closure is done by the 5mm Allen wrench.

The Large Multiscrew Clamp for UNYCO Screws has a particular geometry: the angulation between the two arms is 100° and, when the clamp is mounted, its distance from the skin is approximately 40mm (Fig. 4). These features have been designed to specifically for tibia applications, to permit screw insertion perpendicularly to the bone and to allow for post-operative swelling and for cleaning.

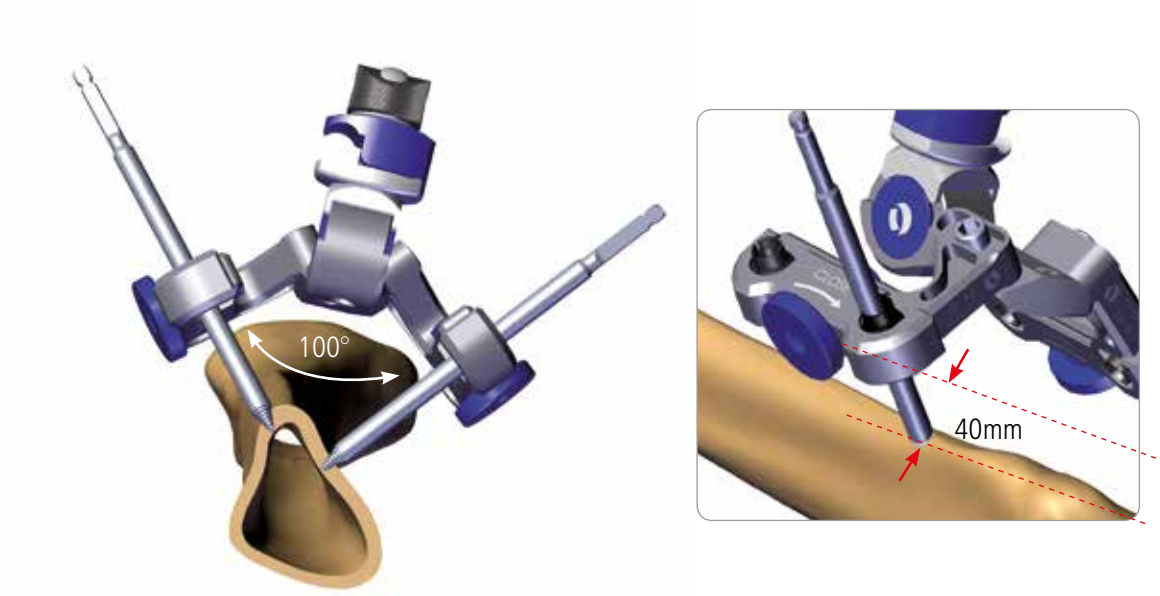


Fig. 4: Large Multiscrew Clamp for UNYCO Screws has a specific geometry design to specifically for tibia applications

The Large Multiscrew Clamp for UNYCO Screws is provided in M configuration, but it can be easily converted to U configuration by unlocking the arms with the 5mm Allen wrench and by re-positioning them (Fig. 5). This feature makes the system flexible and versatile.

Fig. 5: Large Multiscrew Clamp for UNYCO Screws can be easily converted from M to U configuration.

2.2 SCREWS

The Galaxy UNYCO Diaphyseal Tibia Sterile Kit includes two types of screws:

- UNYCO Screws
- UNYCO Cancellous Screws

The main feature of the Galaxy UNYCO Screws is their unicortical anchorage in the bone (Fig. 6).
Both screws are conical, have a 6mm diameter shaft and are made of surgical grade stainless steel.

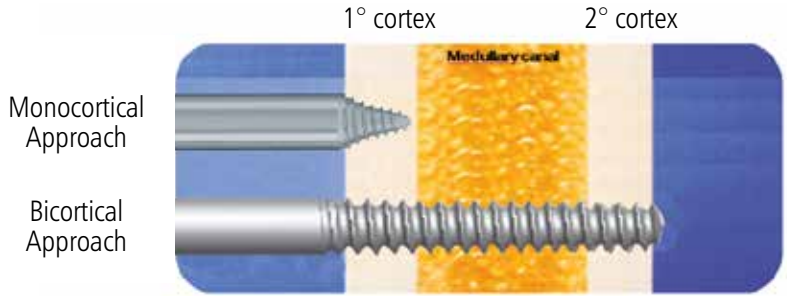


Fig. 6: UNYCO Screws have a unicortical anchorage in the bone

2.2.1 UNYCO SCREWS

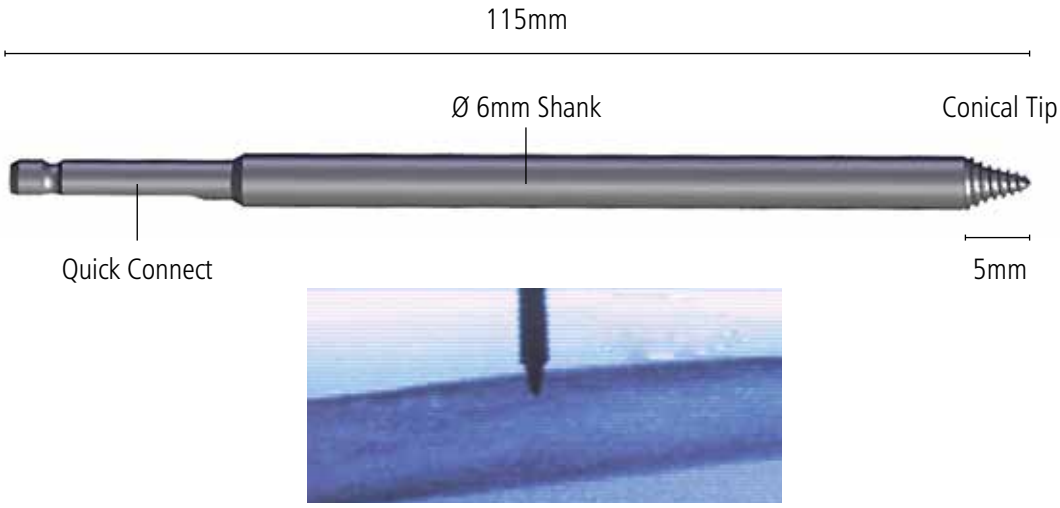


Fig. 7: UNYCO Screw details and fluoroscopy

UNYCO Screws are anchored in the bone cortex and they do not enter the medullary canal (Fig. 7). Bone anchorage is obtained thanks to the conical, self-drilling and self-tapping tip. Thread length is 5mm and has been designed considering the tibia cortical bone characteristics. The conical shape of the tip is designed to produce radial preload: as the screw is inserted, the thinner distal end makes the initial path through the bone. As the screw advances, its diameter increases exerting radial pressure on the cortex. The tip is designed to improve the holding power of the screw.
Screw insertion is performed using specific torque limiter devices either by power drill or manually. This permits to easily reach correct insertion depth.
For power drill application the Power Drill Torque Limiter is included in the standard sterile kit; for manual application, it is possible to order the Limited Torque Wrench.

Mechanical performance: Single screw pull out tests confirmed that UNYCO Screws are characterized by high pull out strength (see Section 4. Mechanical tests).

2.2.2. UNYCO CANCELLOUS SCREWS

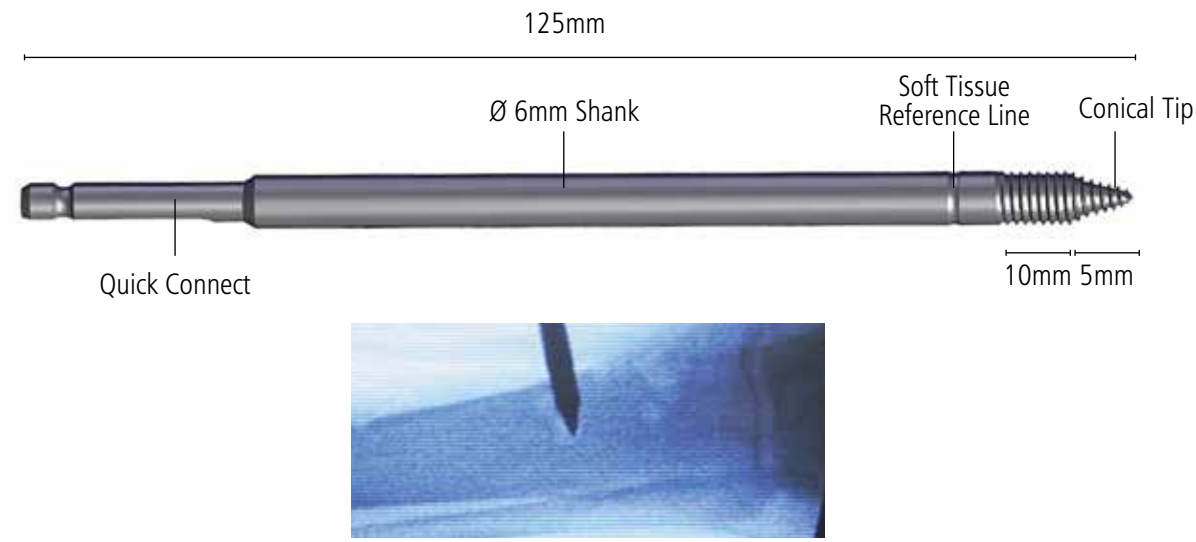


Fig. 8: UNYCO Cancellous Screw details and fluoroscopy

In tibia metaphysis the main bone constituent is cancellous bone [8], which has different microstructure and mechanical properties compared to cortical bone [9]. For this reason, Galaxy UNYCO includes an additional screw type created specifically for cancellous bone. Like the UNYCO screws, UNYCO Cancellous Screws have monocortical anchorage, and they have been designed not to go through the medullary canal (Fig. 8). These screws are characterized by the same conical self-drilling and self-tapping tip of the UNYCO Screws, but they have an additional threaded part 10mm long and of 6mm diameter. This permits cancellous bone purchase.
Screw insertion is performed by using the power drill with torque limiter set at a defined insertion torque. In addition, the shaft of the UNYCO Cancellous Screw has a soft tissue reference line which is used as a reference. The correct insertion depth is reached when the torque limiter stops turning or, when the soft tissue reference line reaches the skin.

Mechanical performance: Single screw pull out tests confirm that UNYCO Cancellous Screws are characterized by high pull out strength (see Section 4. Mechanical tests).

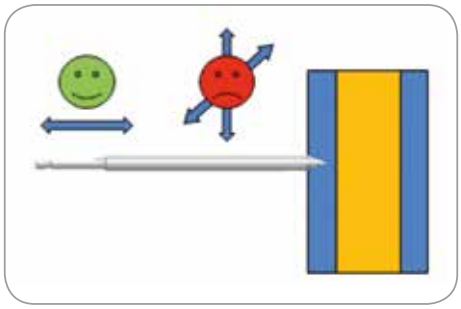
3. GALAXY UNYCO: ADVANTAGES AND BENEFITS

3.1 STABILITY

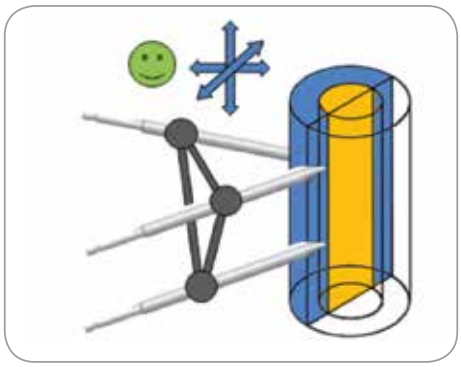
Mechanical tests prove that Galaxy UNYCO has stiffness performance better than or comparable to one traditional temporary external fixation configuration with bicortical screws (see Section 4. Mechanical tests).

The principle behind the stability of the Galaxy UNYCO consists of the use of the specific Large Multiscrew Clamp for UNYCO Screws with at least three UNYCO Screws in the same bone fragment (2 of them must be UNYCO screws 93507). When working in the metaphyseal area, the use of 4 screws is recommended. The clamp should never be applied across the fracture line.

One UNYCO Screw is characterized by high traction/compression strength, whereas it is less efficient when subjected to flexion forces.



The Large Multiscrew Clamp for UNYCO Screws is able to transform flexion forces into traction/compression forces on the screws.
The number of screws used is another important factor that determines the stability of the system. Two screws are not sufficient to provide flexion stability in all directions: flexion is still possible around the line that connect the two screw tips. The use of a clamp with three UNYCO Screws permits creation of a structure stable in flexion in all planes. The fourth screw provides even greater stability (internal reports).



Stability in different bone constituents is achieved by using different screw types: anchorage in tibia diaphysis is obtained by using UNYCO Screws, whereas UNYCO Cancellous Screws are optimized for tibia metaphysis.

3.2 FAST AND EASY

- Controlled screw insertion by means of a torque limiter
- Pre-drilling is not necessary
- All closing mechanisms are tightened with the same Allen wrench
- Snap in feature permits a quick assembly

All these elements allow for fewer steps in the operative technique and make the Galaxy UNYCO ideal for Damage Control Orthopedics and emergency situations.

3.3 DESIGNED FOR A MINIMALLY INVASIVE APPROACH

In the treatment of tibial fractures, external fixation is advantageous because of the relative limited disruption of the blood supply, which is known to be precarious after an open fracture [10].

One of the main features of the Galaxy UNYCO is its monocortical anchorage in the bone. Since the screws do not go through the medullary canal, the technique allows for a minimally invasive approach, which may optimize surgical time and result in cost savings.

3.4 MODULARITY AND ADAPTABILITY

The Galaxy UNYCO is a modular system in which different frame and clamp configurations are possible. Large Multiscrew Clamp for UNYCO Screws can be in M or U configuration in order to create the different frames according to fracture patterns, patient characteristics, to permit management of soft tissues or to have a more convenient access for definitive treatment.
Furthermore, the use of Galaxy Fixation System large single clamps with bicortical screws enlarge the range of possible configurations.

3.5 DESIGNED TO AVOID CONTAMINATION OF THE MEDULLARY CANAL

In severe open tibia fractures, the use of primary external fixation followed by definitive intramedullary nailing is a common procedure [1]. In conventional external fixation systems screws enter the medullary canal. This can be a major drawback as the pins create a direct link between the medullary cavity and outer environment, leading to high infection rates [1, 2]. Literature reports high risk of deep infection (up to 44%) when tibial intramedullary nailing is done after external fixation [3, 4]. Furthermore, the percentage of deep infection can go up to 71% when nailing is done after there is an evidence of pin tract infection [3]. Hence, scientific literature establishes a correlation between infection at the pin site and infection around the nail.
If prolonged external fixation is required or a pin site infection develops, the patient has to be placed in skeletal traction and delayed intramedullary nailing is necessary [11].

The Galaxy UNYCO has been designed to avoid entry into the medullary canal and carries the potential of avoiding contamination of this area prior to subsequent intramedullary nailing. Differently from bicortical screws, UNYCO Screws have the advantage of not passing through the medullary canal and therefore theoretically restricting possible infections to soft tissues only. Clinical investigations are needed to prove this in a clinical setting.

3.6 ABILITY TO CONSTRUCT BRIDGING CONFIGURATIONS WITH THE GALAXY FIXATION SYSTEM

For tibial plateau fractures and very distal tibial fractures, knee and ankle spanning configurations are appropriate to obtain temporary stabilization.

The Galaxy UNYCO has the ability to do bridging configurations by using Galaxy Fixation System large single clamps, rods and Orthofix bicortical bone screws (Fig.9).

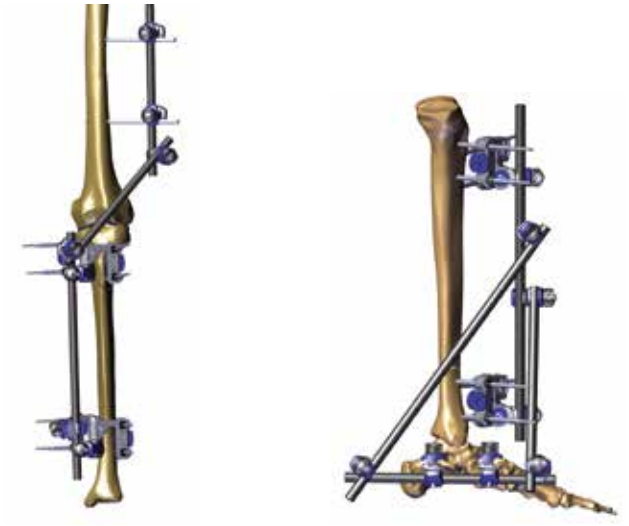


Fig. 9: Examples of knee and ankle spanning configurations

3.7 FEWER STEPS IN THE OPERATIVE TECHNIQUE

Screw overpenetration is a complication that can occur with traditional external fixation systems [12], therefore during screw insertion the surgeon must pay particular attention to not go too far in the second cortex. Intraoperative X-rays are requested to control correct screw insertion [13]. This may increase the total amount of time both surgeons and patients are exposed to X-rays and the total operative time is prolonged.

Galaxy UNYCO has been designed for unicortical bone anchorage and therefore there is no need to control the appropriate insertion in the second cortex. Correct insertion in the cortex is controlled by using the torque limiter or the soft tissue reference line on the screw shaft.

3.8 DESIGNED TO FACILITATE THE CONVERSION FROM TEMPORARY TO DEFINITIVE FIXATION

Many tibial shaft fractures may present different degrees of comminution and are difficult to maintain reduced during nailing procedures, particularly when limited surgical assistance is available. In these circumstances, several procedures, as manual manipulations, sustained traction via a fracture table, a femoral distractor or external fixation, or simple clamp applications, are often required [14] to assist in maintaining the reduction.

Differently from the standard external fixators, the UNYCO screws have been designed not to impede the passage of the nail and therefore the insertion of the implant can be done with the Galaxy UNYCO in place on the tibia. This helps to maintain the fracture reduction, which may optimize surgical time and result in cost savings.

If conversion to definitive stabilization is impeded by the fixator in place, the latter can be partially dismantled. (Fig.10)

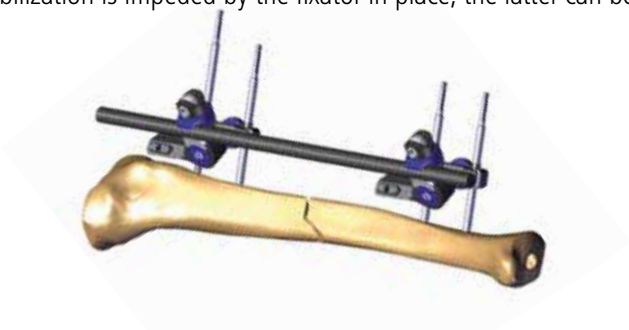


Fig. 10: It is possible to partially dismantle the Galaxy UNYCO during conversion to definitive fixation

3.9 STERILE KIT READY TO BE USED

Galaxy UNYCO is available in a sterile kit ready to be used (Fig. 11), which leads to:
- No sterilization costs
- Easy inventory management
- Easy traceability management

Galaxy UNYCO Diaphyseal Tibia Sterile Kit (99-93506)	
2x Large Multiscrew Clamp for UNYCO Screws	
1x Rod Ø 12mm L 350mm	
8x UNYCO Screw QC Shaft Ø 6mm	
4x UNYCO Cancellous Screw QC Shaft Ø 6mm	
1x Allen Wrench 5mm	
1x Power Drill Torque Limiter	
99-93567	Limited Torque Wrench (out of kit, available upon request)

Fig. 11: Galaxy UNYCO Diaphyseal Tibia Sterile Kit

3.10 MRI CONDITIONAL 1.5 AND 3 T

The clamps and the carbon fiber rods are MRI conditional. For additional details please refer to Instructions for use (PQ MCS).

4. MECHANICAL TESTS

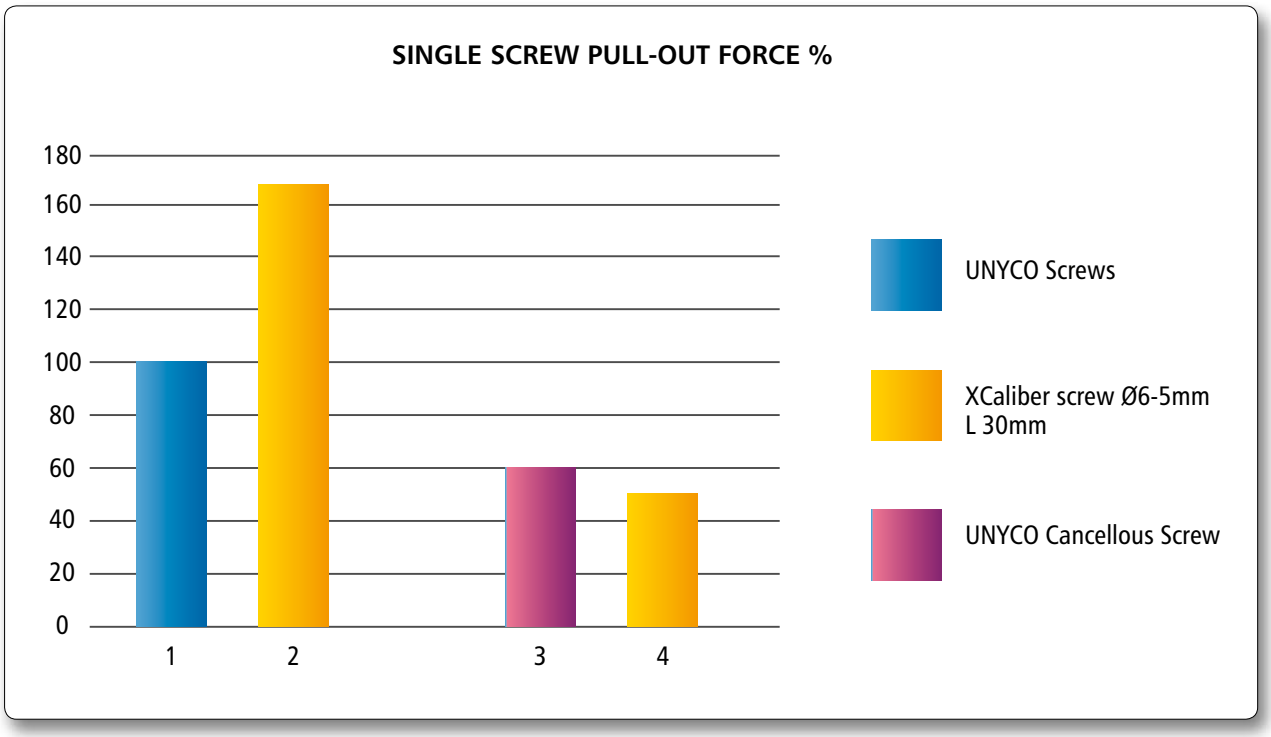
A series of mechanical tests was performed internally to characterize the Galaxy Unyco Diaphyseal Tibia Sterile Kit.

4.1 TESTS ON SCREWS

Commercially available bone analogs simulating cortical bone and cancellous bone were used to evaluate the mechanical features of the UNYCO Screws in comparison to Orthofix bicortical screws.

SINGLE SCREW PULL-OUT

Aim: Evaluation of the pull-out force of UNYCO Screws in comparison to standard XCaliber screws.



1) 5mm purchase on first cortex of bone analog
2) 10mm purchase on cortex of bone analog (5mm on first cortex and 5mm on second cortex)
3) 15mm purchase on cancellous bone analog
4) 30mm purchase on cancellous bone analog

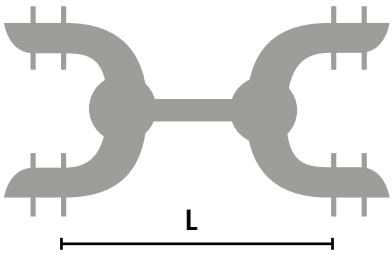
Results: In cortical bone, one UNYCO Screw is able to reach 2/3 pull-out force of a XCaliber screw. This demonstrates how much the screw thread has been optimized. If the thread design had not been improved, the pull-out force of the purchase on one cortex would have been only 50% of the purchase on both cortices. In cancellous bone, one UNYCO Cancellous Screw is able to reach higher pull-out force than one XCaliber screw.

4.2 TESTS ON FRAMES

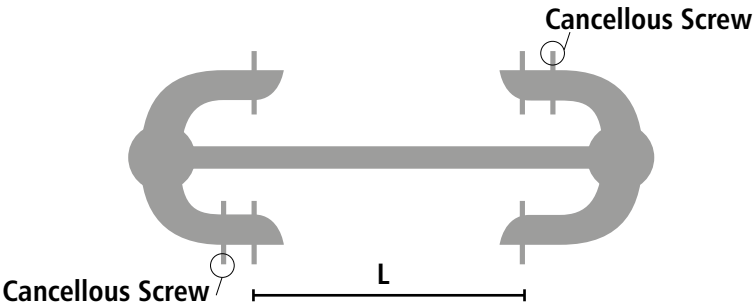
The Galaxy UNYCO was compared to one of the main temporary external fixators on the market.
For the following tests different frame configurations were used.

Galaxy UNYCO:

Frame configuration 1 "Short":
2 Large Multiscrew Clamps for UNYCO Screws
in U configuration
+ 8 UNYCO Screws



Frame configuration 2 "Long":
2 Large Multiscrew Clamps for UNYCO Screws
in U configuration
+ 4 UNYCO Screws
+ 2 UNYCO Cancellous Screws

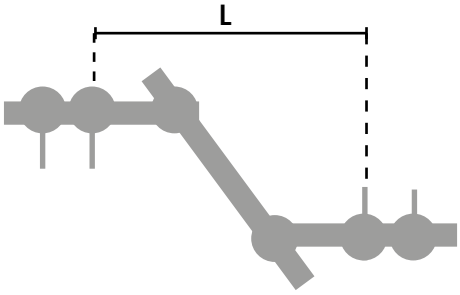


When tested, these two frame configurations showed the minimum and maximum value of mechanical performance. All other possible frame configurations with Galaxy UNYCO Diaphyseal Tibia Sterile Kit gave results within this range of values.

Please refer to the Operative Technique for clinical indications, these two frame configurations only represent the best and worst case scenario in terms of mechanical behaviour.

Competitor:

Standard Z- frame configuration
6 single clamps
+ 3 connecting bars
+ 4 bicortical screws



AXIAL STIFFNESS

Aim: Evaluation of Galaxy UNYCO axial stiffness in comparison to the competitor.

Set up: Frames were mounted as described above. Axial load was applied as shown in Fig.12.

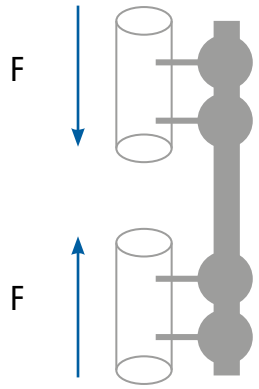
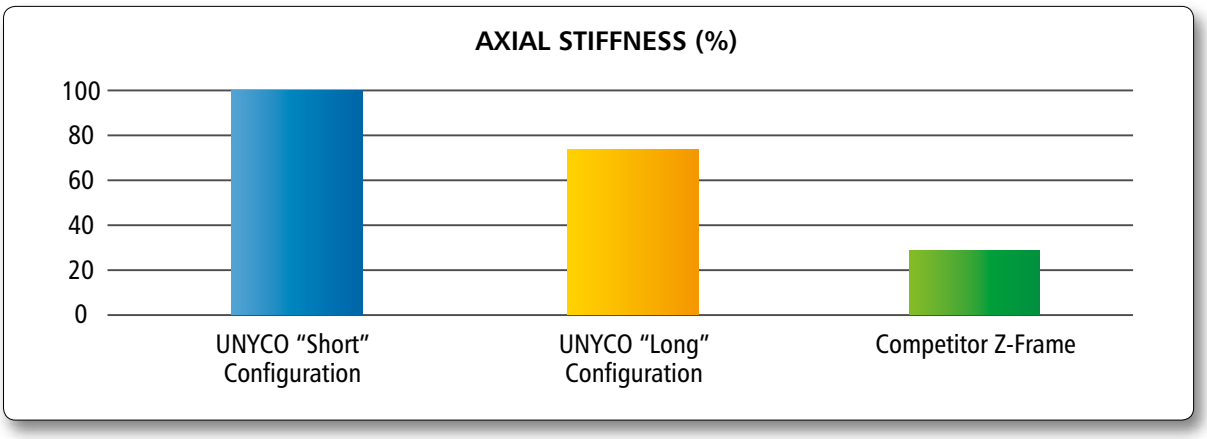


Fig. 12 Stiffness and peak load test scheme

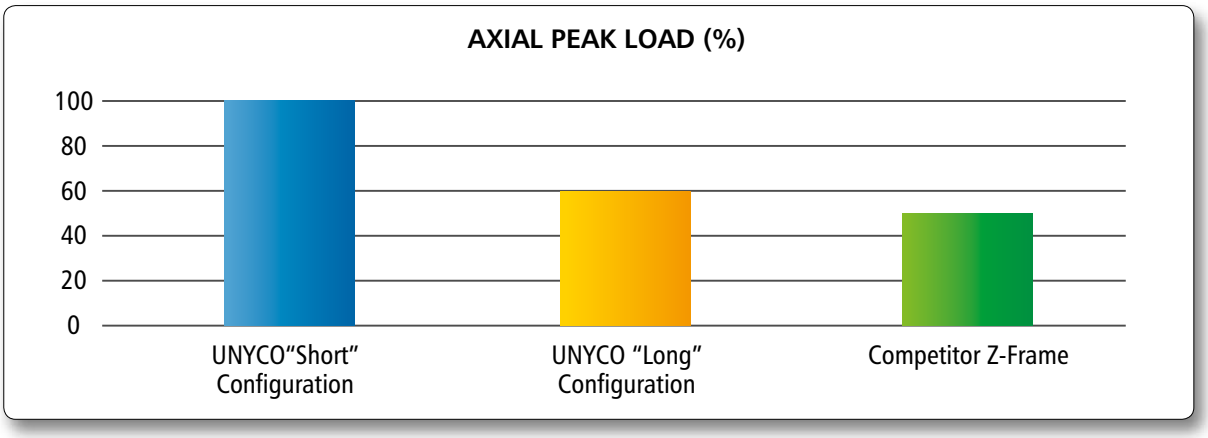


Results: Tests show that the axial stiffness of Galaxy UNYCO is higher than the competitor.

AXIAL PEAK LOAD

Aim: Evaluation of Galaxy UNYCO peak load (failure load) in comparison to the competitor.

Set up: Frames were mounted as described above. An increasing force was applied as shown in Fig. 12 until frame failure was recorded.



Results: Tests show that the Galaxy UNYCO failure load is higher than the competitor.

ML DISPLACEMENT

Aim: Evaluation of Galaxy UNYCO resistance to ML displacement in comparison to the competitor.

Set up: Frames were mounted as described above. One stump was fixed and an ML force was applied to the other one and the displacement was recorded, Fig. 13.

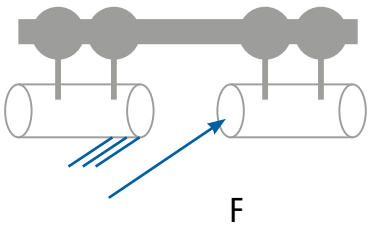
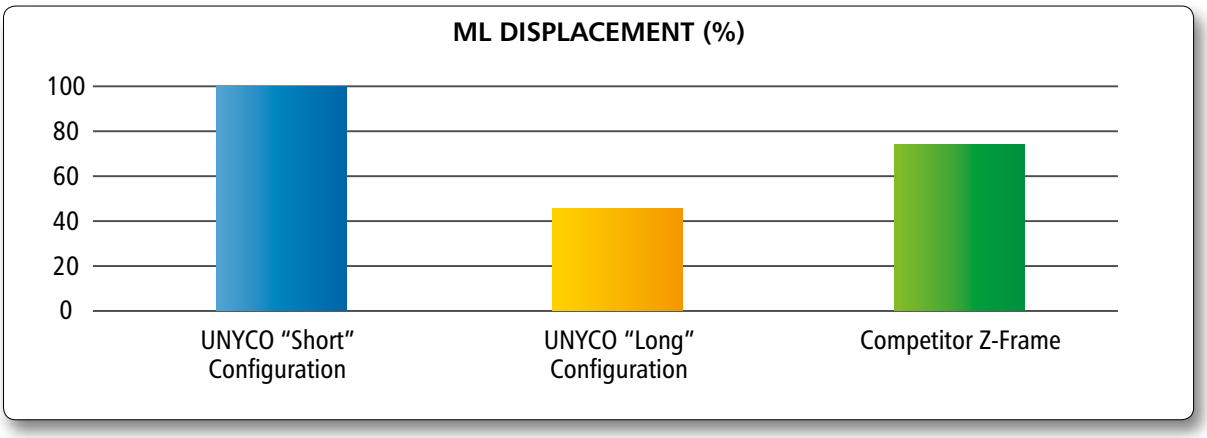


Fig. 13 ML displacement test scheme



Results: Tests show that the Galaxy UNYCO "short" configuration has higher resistance to ML displacement than the competitor. The Galaxy UNYCO "long" configuration has lower resistance to ML displacement than the competitor, but it reaches acceptable levels of resistance.

AXIAL MULTICYCLE

Aim: Evaluation of the performance of the Galaxy UNYCO subjected to repetitive loading.

Set up: Frames were mounted as described above. Alternate repetitive loading was applied as shown in Fig. 14 for 50000 cycles.

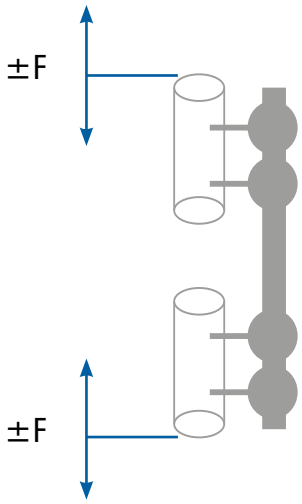
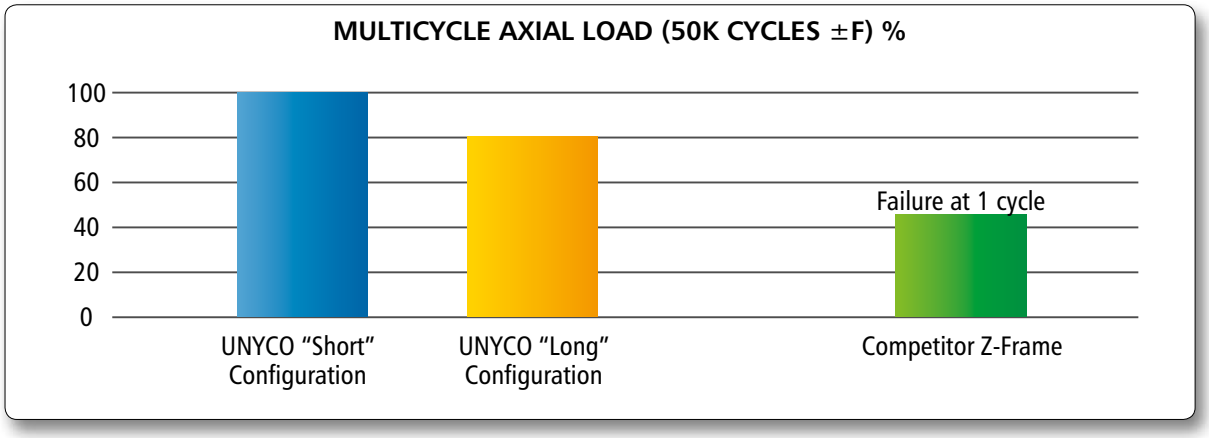


Fig. 14 Axial multicycle test scheme



Results: Multicycle tests show that the Galaxy UNYCO is able of withstand higher repetitive load than the competitor.

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