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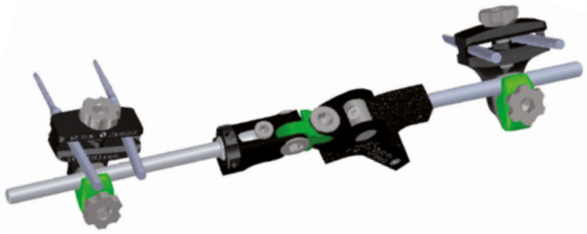
Galaxy Fixation™

Wrist System



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Galaxy Wrist

1. INTRODUCTION

Galaxy Wrist is an innovative external fixator intended for the following indications:

- intra-articular or extra-articular fractures and dislocations of the wrist with or without soft tissue damage
- polytrauma
- carpal dislocations
- unreduced fractures following conservative treatment
- bone-loss or other reconstructive procedures
- infection

This document gives a comprehensive description of Galaxy Wrist's technical and biomechanical features. The innovative technical aspects of the components and the whole system are presented, thus demonstrating the unique advantages and benefits that Galaxy Wrist offers.

2. SYSTEM COMPONENTS: DESCRIPTION AND TECHNICAL FEATURES

Galaxy Wrist is a modular system composed of:

- an articulated wrist module
- clamps (small multiscrew clamps and small clamp)
- rods (aluminum alloy L-rod and carbon fiber rods)

It must be used in combination with Orthofix bone screws.

2.1 ARTICULATED WRIST MODULE ⚠MR

The most innovative component of the Galaxy Wrist is the articulated wrist module that is used in bridging configurations (Fig. 1).

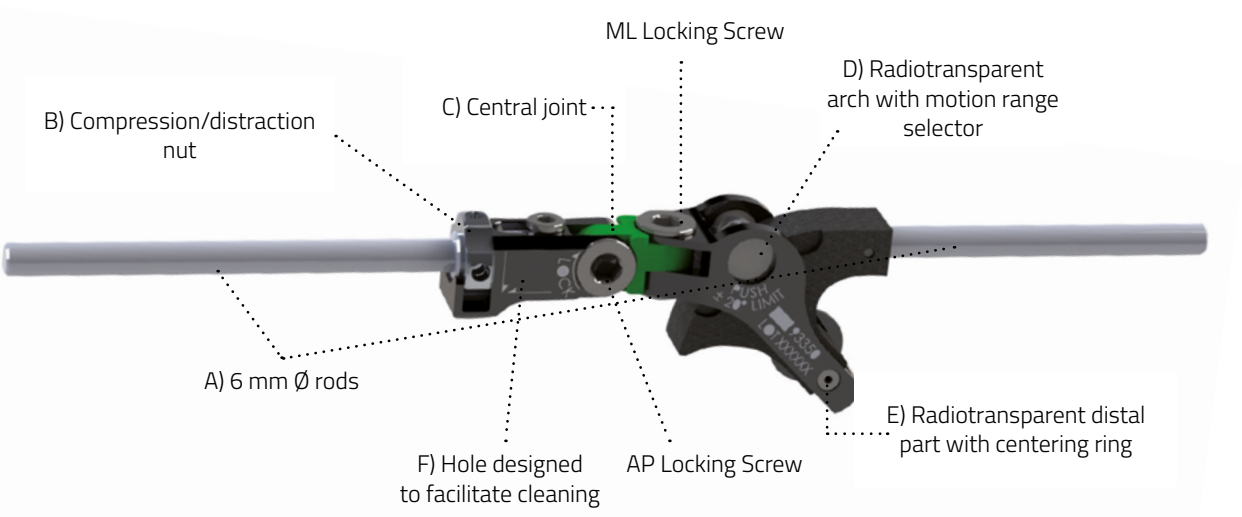


Fig. 1: Articulated wrist module details

A. 6 mm Ø rods

The wrist module has 6 mm Ø rods that are made of aluminum alloy to reduce fixator weight. They can be connected to Galaxy small multiscrew clamps and small clamps.

B. Compression/distraction nut

Distraction up to 7 mm is obtained by turning the compression/distraction nut by hand or by using the universal Allen wrench (Fig. 2). After distraction, locking is performed by tightening the locking screw. This screw is riveted, preventing accidental loss.

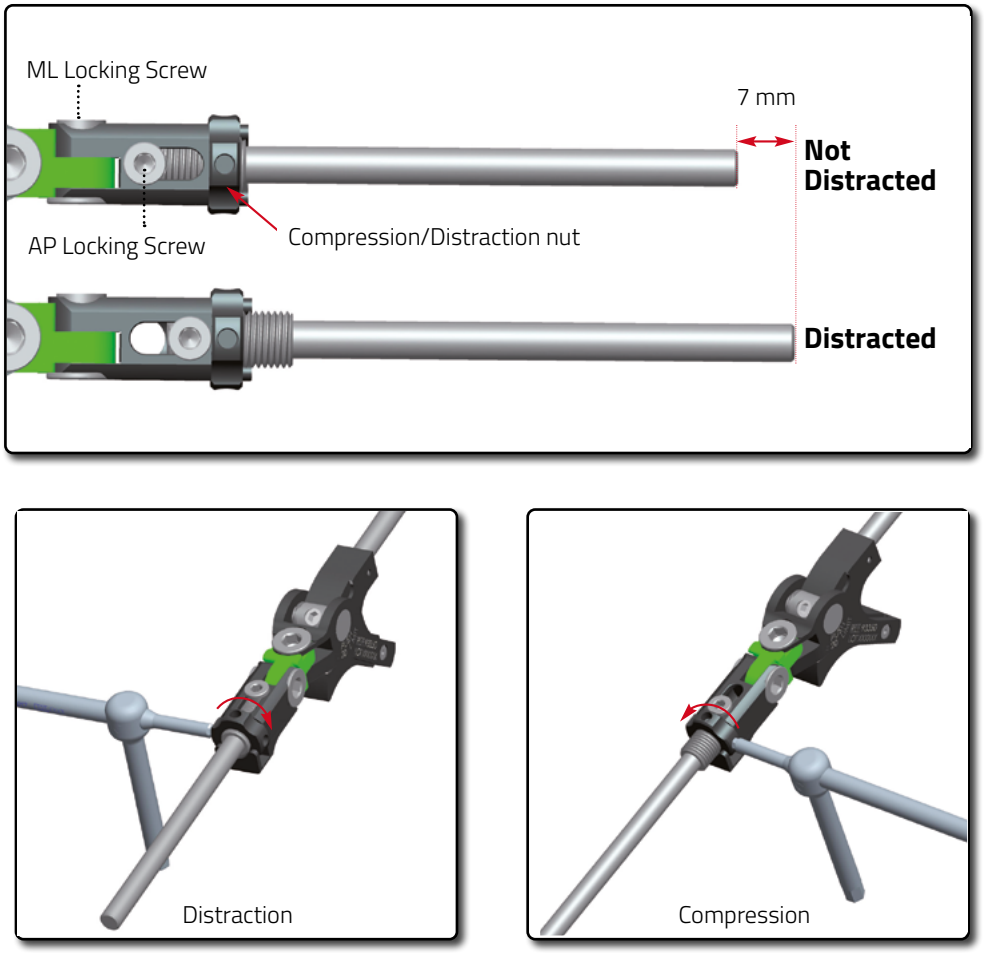


Fig. 2: Distraction up to 7 mm can be obtained

C. Central joint

The central joint of the articulated wrist module permits to articulate the fixator up to +/-45° in the ML (frontal) and AP (sagittal) planes (Fig. 3). These movements are independent and regulated by locking screws. This solution makes the system highly maneuverable and adaptable after positioning of the bone screws and during the fracture reduction procedures.

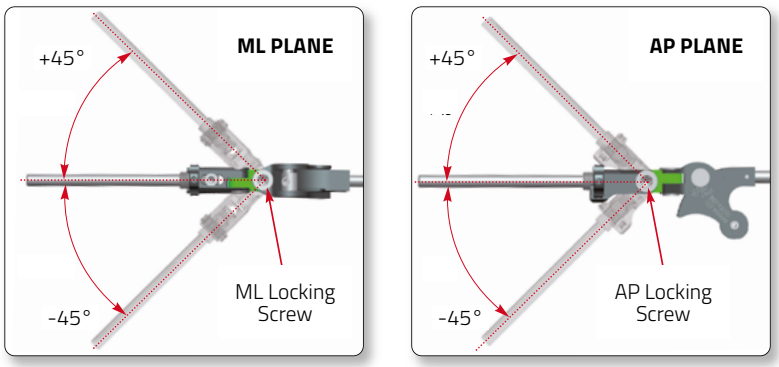


Fig. 3: The central joint permits to adapt the wrist module during fracture reduction

Once the wrist module is mounted in the correct position, locking screws are tightened. Locking screws are accessible to both sides of the module and are riveted. For simplicity, the same universal Allen wrench can be used to tighten them.

D. Radiotransparent arch with motion range selector

The articulated wrist module, thanks to the motion range selector, permits wrist mobilization at controlled angles (+/-20° instead of +/-40°) (Fig. 4). By pushing the motion range selector in its outer seat with the Allen wrench it is possible to gain 40° of freedom. By pushing the motion range selector in its inner seat with the Allen wrench it is possible to gain 20° freedom (Fig. 4).

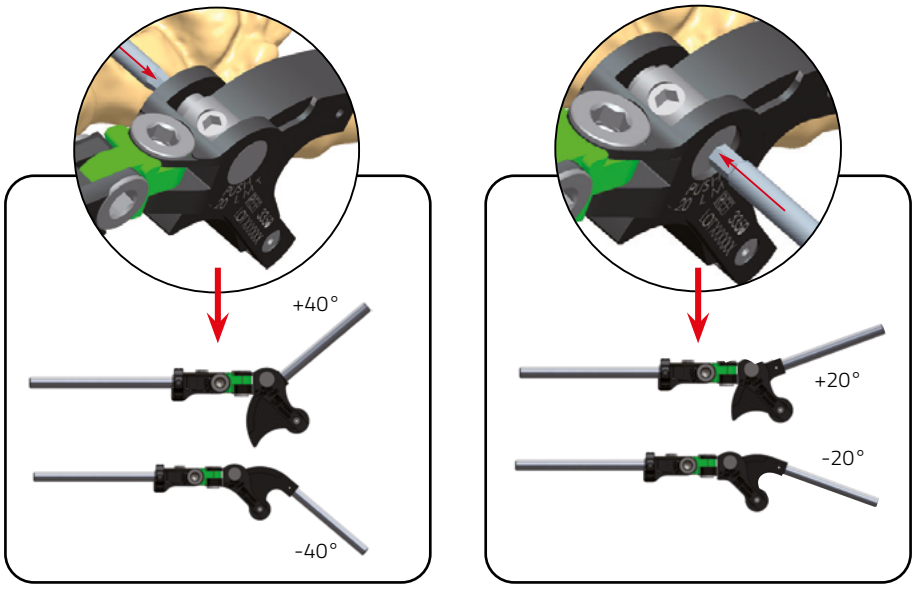


Fig. 4: Motion range selector permits to choose defined ranges of wrist mobilization

Flexion-extension of the wrist can be allowed about 3 weeks after surgery in order to recover wrist functionality faster. The articulation arch is made of composite material to combine high rigidity with radiotrasparency.

E. Radiotransparent distal part with centering ring

The distal part is made of aluminum alloy with a low thickness. Material choice and thickness have been optimized to have radiotransparency. The distal part has a centering ring with a hole for insertion of a K-wire. This K-wire can be used as an indicator of the alignment between the center of rotation of the wrist joint and the center of rotation of the module in the frontal plane. When K-wire and centering ring are aligned, it means that the fixator is orthogonal to the AP plane (Fig. 5).

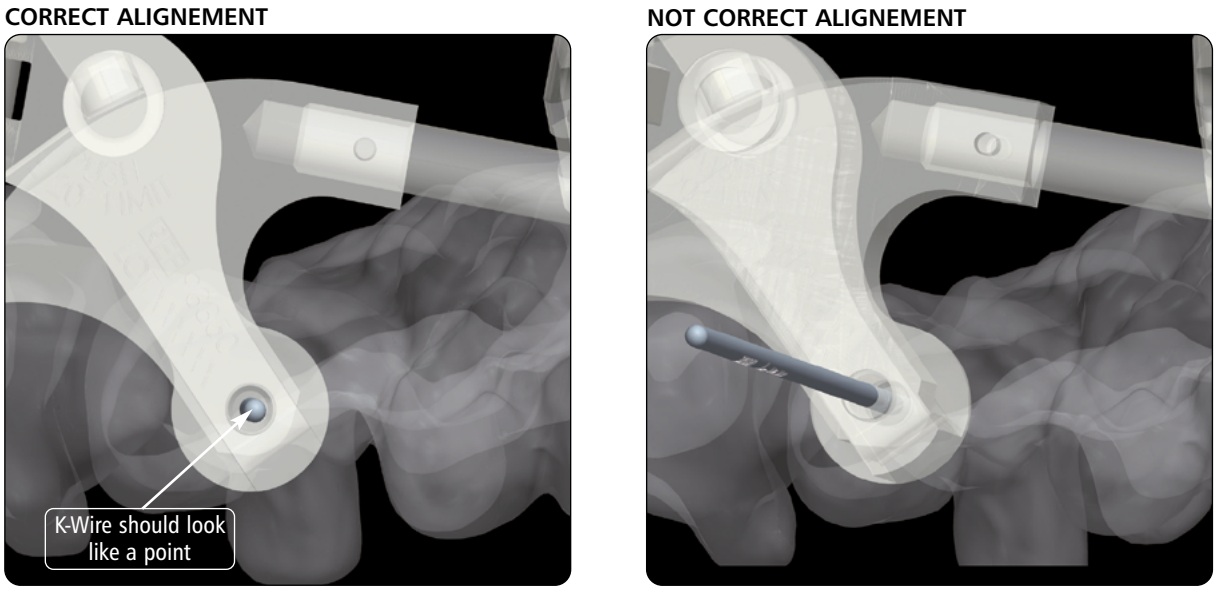


Fig. 5: Correct alignment of the fixator can be easily checked

F. Hole designed to facilitate cleaning

By turning the wrist module upside down, it is possible to notice a hole (Fig. 6): this has been designed to facilitate fixator cleaning.

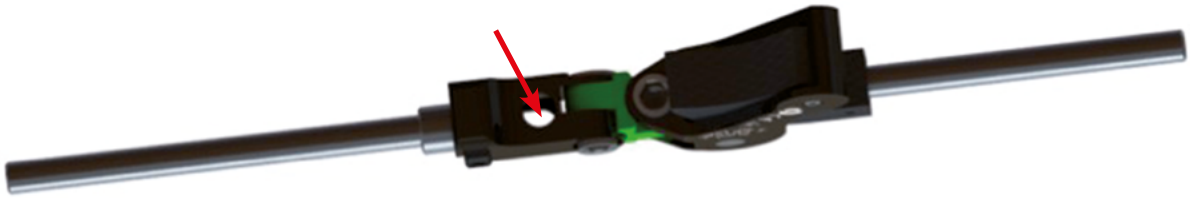


Fig. 6: Hole designed for easy cleaning

2.2 CLAMPS

2.2.1 Small Multiscrew Clamps

The small multiscrew clamps are available in two sizes: long and short (Fig. 6).

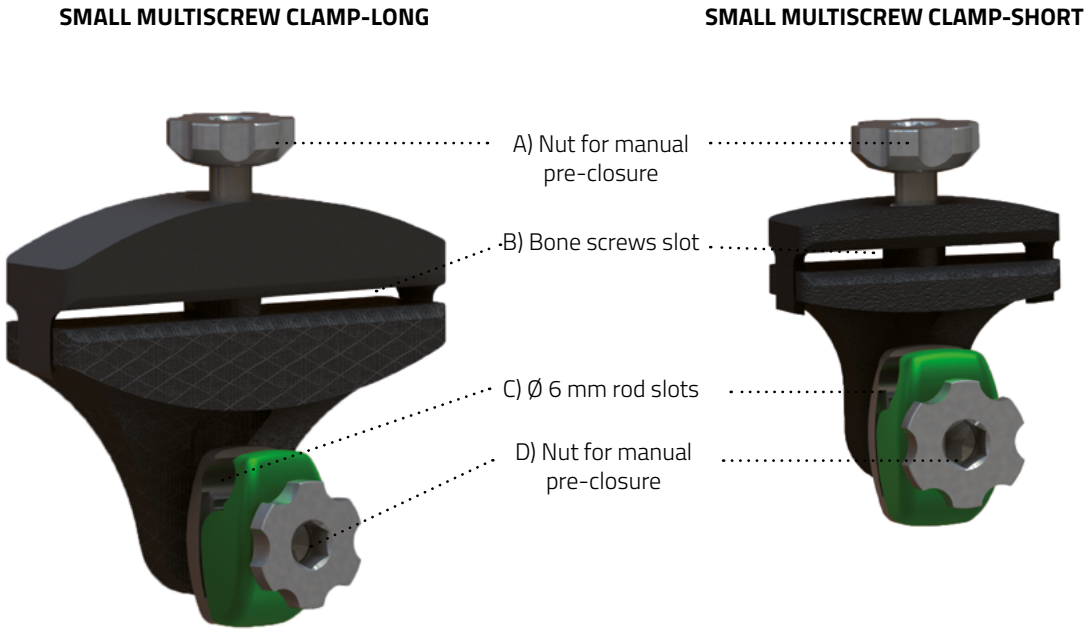


Fig. 6: Small multiscrew clamps details

The small multiscrew clamp-long can be used both in bridging and non-bridging configurations. Especially in non-bridging configurations satisfactory radiotransparency at the fracture site is fundamental. The small multiscrew clamp-long is made of plastic material to permit easy fracture visualization.

A. Nut for manual pre-closure

Both clamps have locking screws with a nut that permits preliminary manual pre-closure and subsequent definitive closure by using the universal allen wrench. These screws are riveted, preventing accidental loss.

B. Bone screws slot

Both clamps permit the use of 2 bone screws having a shaft diameter of either 3 or 4 mm.
Bone screws can be inserted with variable angulation to become convergent/divergent and variable interaxis (distance from each other). In the short clamp, bone screws can be mounted with interaxis between 10 and 24 mm, in the long one between 12 and 46 mm.

C. Ø 6 mm rod slot

The part of the clamp where 6 mm Ø rods are accommodated can rotate of 360° (Fig. 6). Furthermore, they have a click-clamp design that permits rapid connection of the rods to the clamp, thus making the assembly faster. This permits a fast frame assembly.

2.2.2 Small Clamp

The small clamp (Fig. 7) permits independent screw placement.

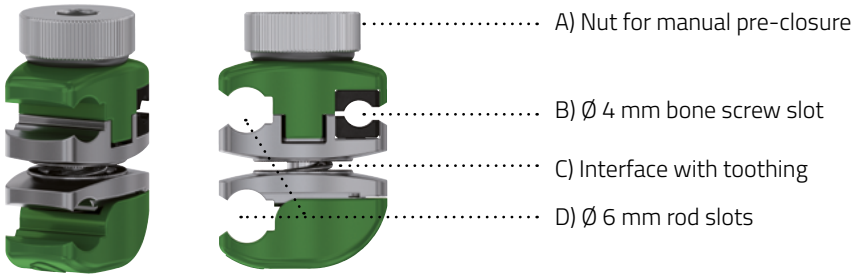


Fig. 7: Small clamp details

A. Nut for manual pre-closure

Like small multiscrew clamps, the small clamp has locking screws with a particular head design for manual pre-closure and subsequent final closure by using the universal Allen wrench. These screws cannot be disassembled, as they are riveted. Therefore, this clamp is ready to be used and there is no need of having spare parts.

B. Bone screw slot

The small clamp accepts 4 mm Ø bone screws. It is made of titanium and surgical grade stainless steel and it is characterized by inserts made of plastic material.

C. Ø 6 mm rod slot

Like small multiscrew clamps, this clamp accepts 6 mm Ø rods. 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.

D. Interface with toothing

The presence of an interface with toothing provides "friction clutch" between the two parts of the clamp avoiding sliding during assembly (Fig. 9). This enhances torsional strength (internal report) thus contributing to the system's stability.

2.3 RODS

2.3.1 Aluminum alloy L-rod

The L-rod (Fig. 9) is 176 mm long and has a diameter of 6 mm. Is made of aluminum alloy, it is single use and it is used in non-bridging assemblies.

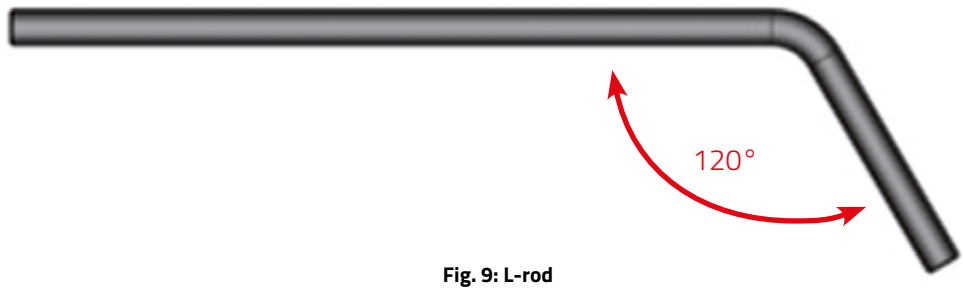


Fig. 9: L-rod

2.3.2 Carbon fiber rods ⚠MR

Carbon fiber rods (Fig. 10) are available in different lengths (from 60 mm to 200 mm), are single use and have a diameter of 6 mm.

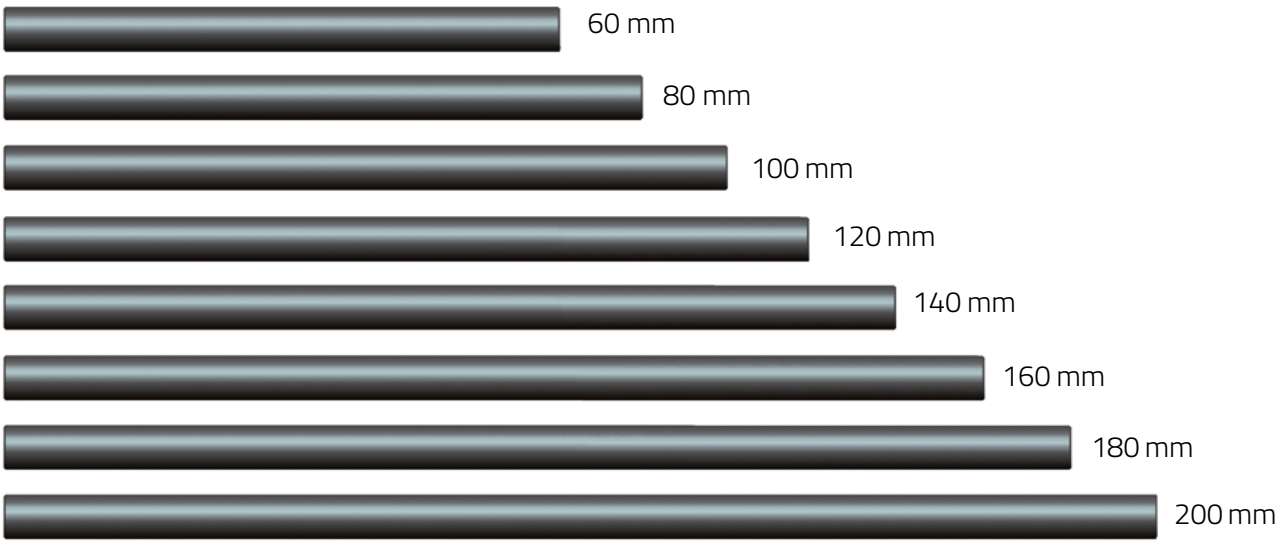


Fig. 10: Carbon fiber rods

3. GALAXY WRIST: ADVANTAGES AND BENEFITS

3.1 EASY, FAST AND STABLE

Galaxy Wrist is easy, fast and stable because:
- simple straightforward operative technique
- all locking screws are tightened with the same Allen wrench
- click-clamp feature permits a quick assembly
- wrist component is supplied assembled
- technical solutions such as the interface with toothing and the particular rod slots of the clamps contribute to the system stability.

3.2 OPTIMAL MANEUVERABILITY DURING FRACTURE REDUCTION

In distal radius, fracture treatment should aim at obtaining and maintaining an anatomical reduction as the incidence of sequelae of fractures healed in an anatomical position is lower than in malunited fractures [1].

The wrist module is characterized by high maneuverability thanks to the central joint that permits angulations up to ± 45° in the ML (frontal) and AP (sagittal) planes. Therefore, after insertion of the bone screws and clamps, the fixator geometry does not limit bone movement by manipulation during fracture reduction.

3.3 VERSATILITY

Considering the heterogeneity of distal radius fractures, external fixation nowadays should give the options of bridging and non-bridging applications, controlled adjustment and wrist mobilization with the fixator in place [2].

Galaxy Wrist with its components is a highly versatile external fixation system:

- it permits both bridging and non-bridging configurations (Fig. 11)
- in bridging configurations it is possible to select the range of wrist mobilization (± 20° or ± 40° of flexion-extension)
- bone screws can be placed independently with small clamps, and at variable angles and distance from each other with multiscrew clamps (Fig. 11)

Fig. 11: Bridging and non-bridging configurations are possible

3.4 UNOBSTRUCTED VIEW OF THE FRACTURE SITE

Radiotransparency is an advantageous feature for an external fixator. If a unilateral external fixator for distal radius fractures is not radiotransparent, pins need to be placed properly to allow for AP and ML view of the fracture site when the fixator is in place. If visualization in one plane remains difficult, additional procedures need to be performed [2, 3] and the amount of time both surgeons and patients are exposed to X-rays is prolonged [3].

The Galaxy Wrist provides an unobstructed view of the fracture site thanks to:

- the positioning out of the radius axis in AP plane and the "C-shape" design of the wrist module (Fig. 12)

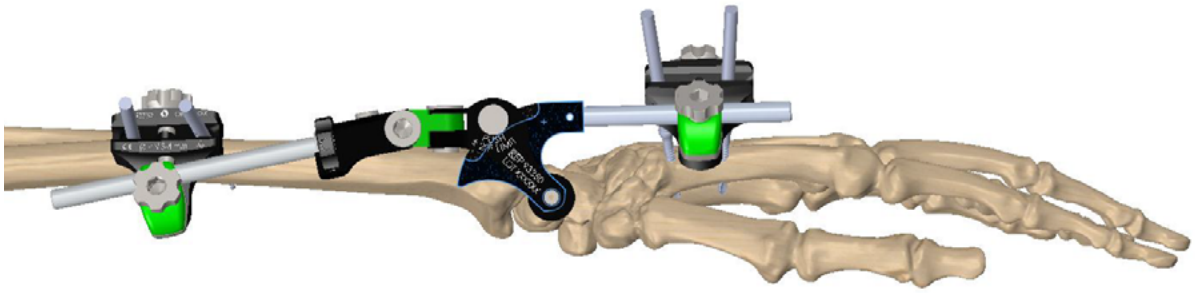


Fig. 12: Site of fixator placement in the wrist

- the satisfactory radiotransparency of the wrist module (Fig. 13) and the small multiscrew Clamp-Long

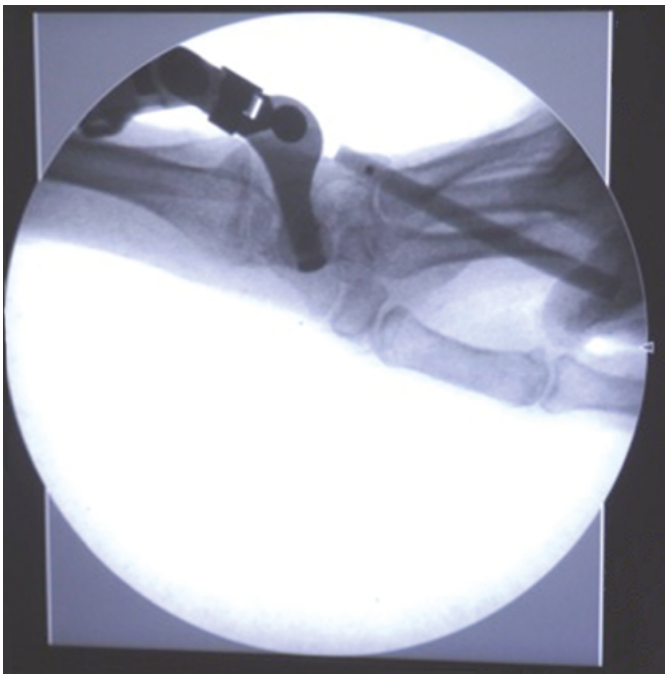


Fig. 13: Wrist module radiotransparency

3.5 EARLY MOBILIZATION/ARTICULATION

One of the most important goals of treatment is to restore wrist mobility and function [4]. Early mobilization during the fixation period potentially minimizes stiffness of the wrist, and it may facilitate articular cartilage repair [5]. Furthermore, it is thought to result in an earlier return to function with reduced complications, with practical advantages for the patient [4]. Thanks to the articulated wrist module, Galaxy Wrist permits flexion-extension of the wrist and allows patients to start rehabilitation early.

3.6 EASY AND EFFECTIVE COMPRESSION/DISTRACTION

With Galaxy Wrist compression or distraction up to 7 mm can be easily obtained by turning the compression/distraction nut on the articulated wrist module.

3.7 COMPATIBILITY WITH OTHER FIXATION SYSTEMS (K-WIRES, PLATES,...)

Treatment of complex fractures can be done by combining different fixation methods [6].

Literature reports that augmentation of external fixation with K-wires increases stability of distal radial fractures [7, 8], reduces the need for excessive traction [7, 8] and avoids late collapse [2]. K-wires also help to maintain palmar tilt [7]. Furthermore, severely impacted fragments may not be reduced simply with traction and require percutaneous manipulation using supplementary K-wires [7, 9].

The distal part of the wrist module has been created with a special "C-shaped" design to permit easy and unobstructed application of additional K-wires (Fig. 14).

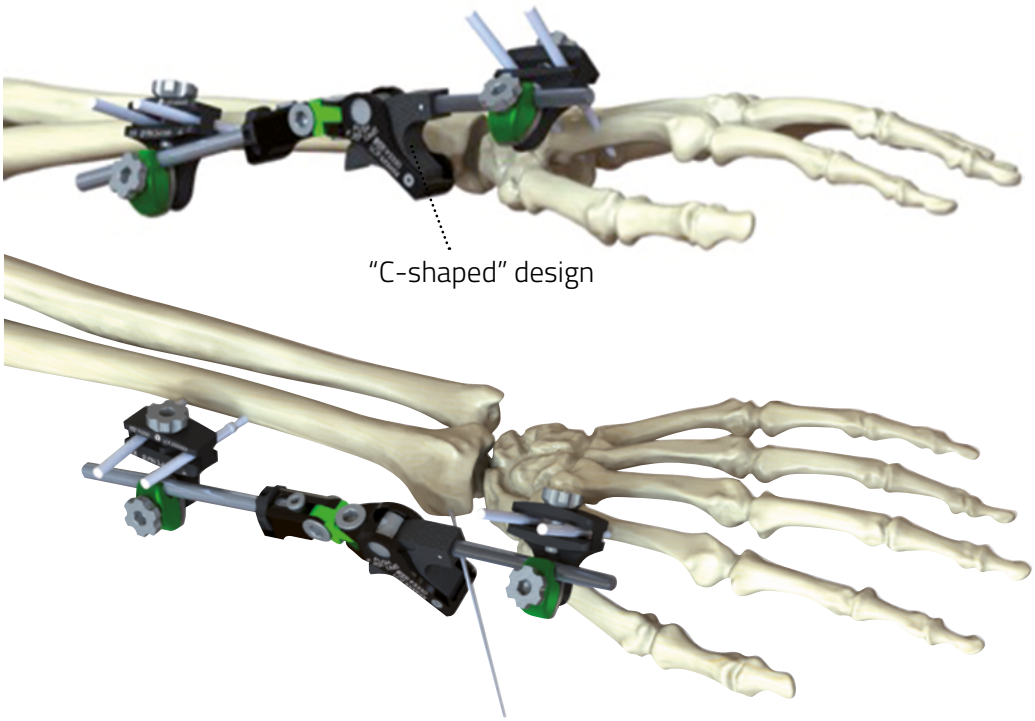


Fig. 14: The particular C-shape design permits the use of K-wires

The combined use of Galaxy Wrist with plates and screws is possible as well.

3.8 LOW PROFILE FOR ENHANCED PATIENT COMFORT

When external fixation devices are bulky, they are inconvenient for patients and interfere with daily activities, personal hygiene and clothing [10].

Galaxy Wrist components have been created to be low profile and with reduced dimensions for enhanced patient comfort.

3.9 LIGHTWEIGHT

It is well-accepted that a lightweight design improves wearing comfort for the patients [11].

Galaxy Wrist weighs less than other external fixators for distal radius fractures on the market (internal reports) (Fig. 15).

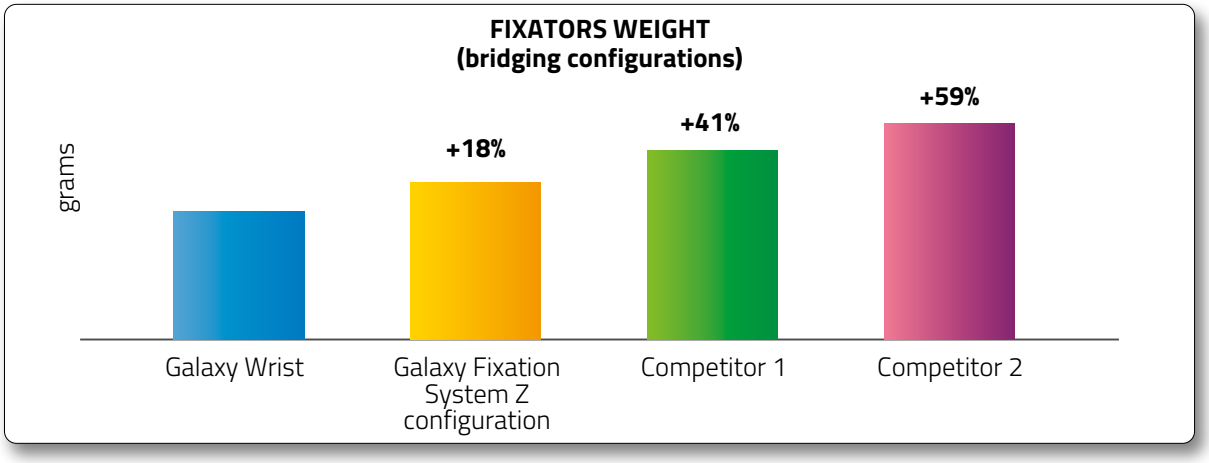


Fig. 15: Galaxy Wrist is lighter than other fixators on the market

Furthermore, the use of L-rods for "Z configurations" permits a decrease in the number of clamps needed and therefore to reduces the total weight of the fixator.

3.10 STERILE KIT READY TO BE USED

Galaxy Wrist is available also in a sterile kit ready to be used with basic components, avoiding sterilization costs, time, possibly dull drills, and missing components (Fig. 16).

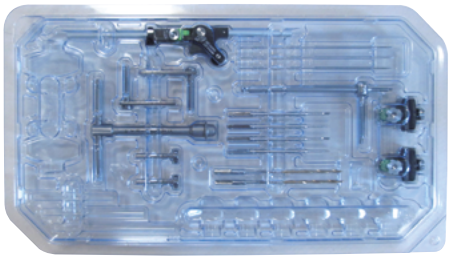


Fig. 16: Galaxy Wrist sterile kit

3.11 MRI CONDITIONAL

The articulated wrist module, the clamps and the carbon fiber rods are MRI conditional. For additional details please refer to Instructions for use (PQ GAL).

4. MECHANICAL TESTS

A series of mechanical tests were performed internally to evaluate the mechanical features of Galaxy Wrist.

4.1 SCREW SLIPPING TEST

Aim: Evaluation of the axial slipping force of the screw in the small multiscrew clamps in comparison to one main competitor on the market.

Galaxy Wrist configurations:
1. small multiscrew clamp LONG + 2x 3 mm Ø bone screws
2. small multiscrew clamp LONG + 2x 4 mm Ø bone screws
3. small multiscrew clamp SHORT + 2x 3 mm Ø bone screws

Competitor configuration:
4. radiolucent multiscrew clamp + 2x 3 mm Ø bone screws

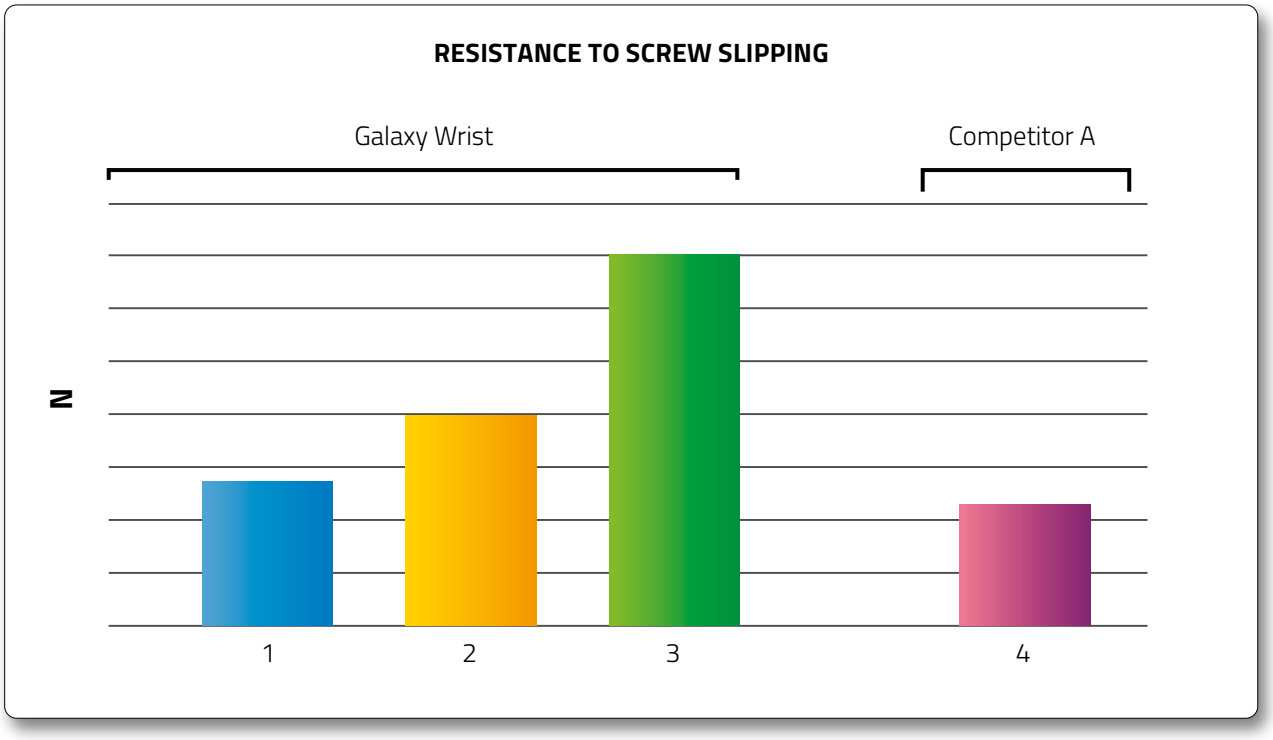


Fig. 17: Resistance to screw slipping

Results: Galaxy Wrist small multiscrew clamps are characterized by higher resistance to screw slipping than the radiolucent multiscrew clamps of one main competitor on the market.

4.2 AXIAL STIFFNESS TEST

Aim: Evaluation of Galaxy Wrist axial stiffness in comparison to its two main competitors on the market. Both standard bridging and non-bridging configurations were tested.

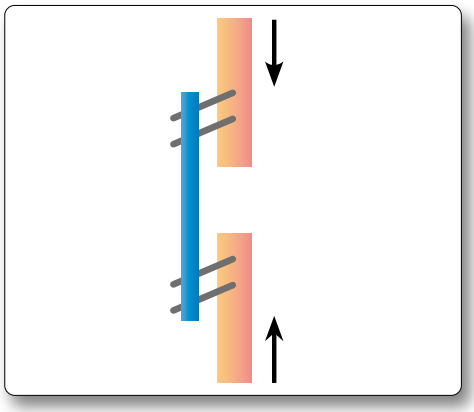
Standard bridging configuration

Galaxy Wrist configurations:
1. 2 small multiscrew clamps LONG
   + carbon fiber rod + 3 mm Ø bone screws

2. 2 small multiscrew clamps LONG
   + articulated wrist module + 3 mm Ø bone screws

Competitor B configurations:
3. 2 multiscrew clamps + rod + 3 mm Ø bone screws
4. 6 single screw clamps + 3 rods + 4 mm Ø bone screws

Competitor C configuration:
5. 2 single screw clamps + 3 rods + 3-4 mm Ø bone screws



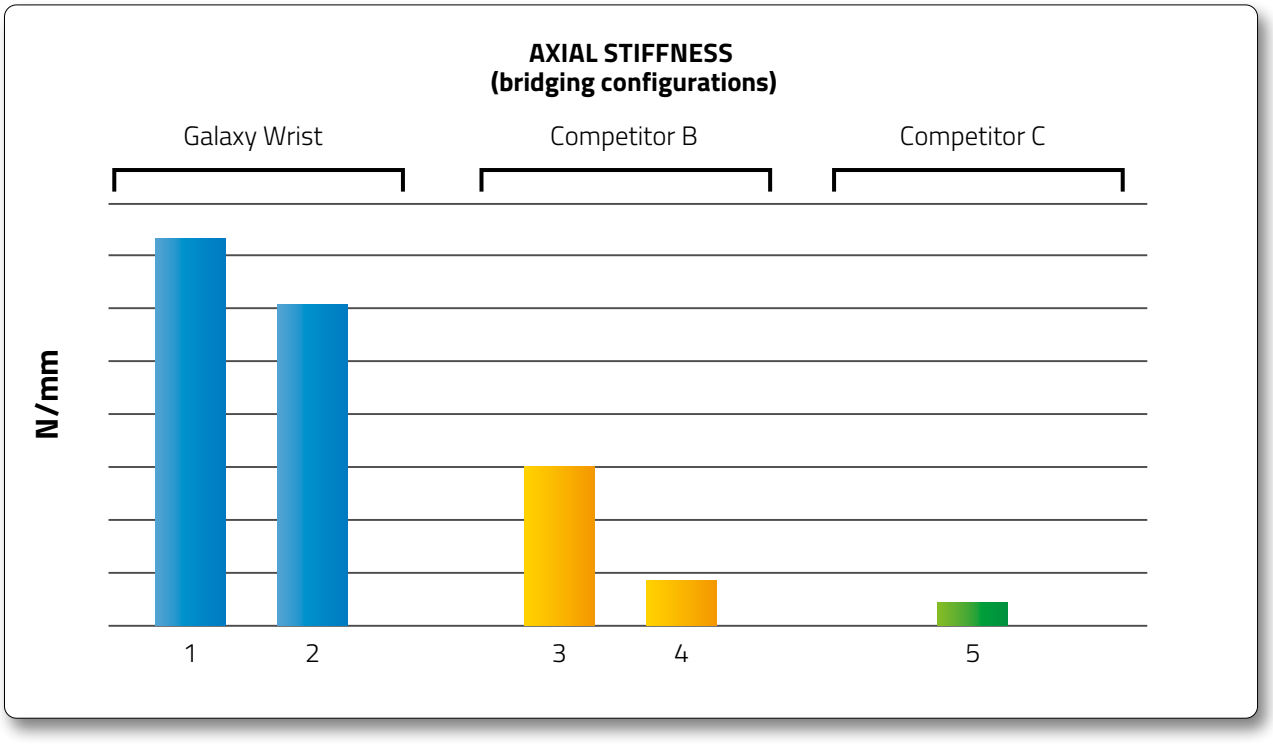


Fig. 18: Axial Stiffness (bridging configurations)

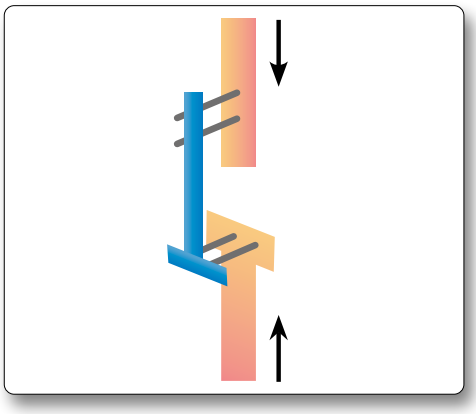
Standard non-bridging configuration

Galaxy Wrist configurations:
1. 2 small multiscrew clamps SHORT
+ carbon fiber rod + 3 mm Ø bone screws

2. 2 small multiscrew clamps SHORT
+ L-rod + 3 mm Ø bone screws

Competitor B configurations:
3. 2 multiscrew clamps + rod + 3 mm Ø bone screws
4. 6 single screw clamps + 3 rods + 4 mm Ø bone screws

Competitor C configuration:
5. 2 single screw clamps + 3 rods + 3-4 mm Ø bone screws



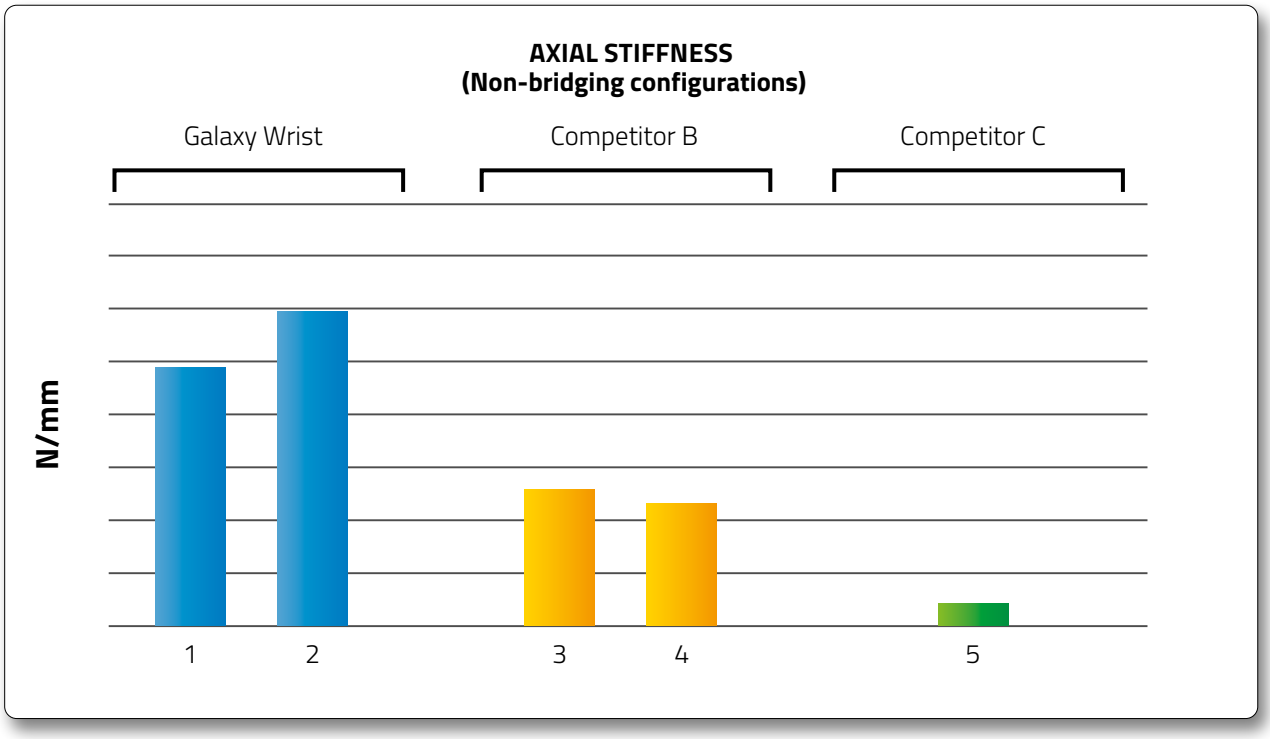


Fig. 19: Axial Sitffness (non-bridging configurations)

Results: Galaxy Wrist in both bridging and non-bridging configurations is characterized by higher axial stiffness than its two main competitors on the market.

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