



# Radiolucent Wrist Fixator

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For years, clinical decision-making was based primarily on physician knowledge and expert opinion. Now, the medical community is searching for measurable outcomes “validating” efficacy of treatments. Evidence Based Medicine (EBM) is an approach that integrates individual clinical expertise with the best available evidence when making decisions about patient treatment. (Nierengarten MB et al. Using Evidence Based Medicine in Orthopaedic Clinical Practice: The Why, When, and How-To Approach. Medscape Orthopaedics & Sports Medicine. 2001; 5[1]). Over the last few years, there has been a significant growth in Evidence Based Medicine.

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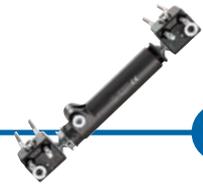
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# Radiolucent Wrist Fixator

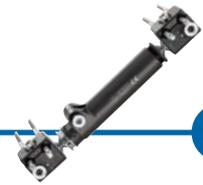


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# Radiolucent Wrist Fixator



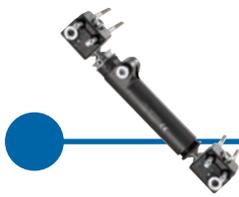
## 1. INTRODUCTION

The Radiolucent Wrist Fixator is part of Orthofix External Fixation Systems which are intended as a means to stabilize bone segments in a broad range of indications, including fractures, joint fusion, joint distraction, bone transport, lengthening and angular corrections.

In particular, the Radiolucent Wrist Fixator indications include:

- Fractures of the distal radius - intrarticular or extrarticular
- Preliminary fixation before ORIF
- Fractures with open or closed soft tissue damage
- Polytrauma ("damage controlled surgery", temporary or definitive)
- Burns or other skin damage – wrist, carpus, forearm
- Fractures and dislocation in combination with
  - severe soft tissue damage
  - bone-loss or other reconstructive procedures
  - damage to nerves-and/or blood vessels
- Loss of reduction after initial treatment
- Infections

This aim of this document is to give a detailed description of the Radiolucent Wrist Fixator and to underline the advantages and benefits that it can offer to both surgeons and patients.



# Radiolucent Wrist Fixator

## 2. TECHNICAL FEATURES AND BENEFITS

### LOW PROFILE AND ERGONOMIC UNILATERAL CONFIGURATION

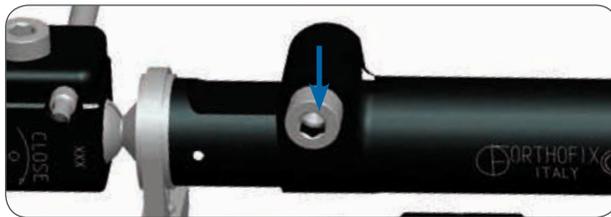
Most external fixation devices are bulky and inconvenient for patients, interfering with daily activities, personal hygiene and clothing [1]. It has been suggested that external fixators for distal radius fractures should be preferably low profile and unilateral configurations are considered more desirable [2]. Ergonomics is another important aspect for patient comfort and safety.

The Radiolucent Wrist Fixator has been designed to have low profile and advanced ergonomics for enhanced patient comfort. The frame is compact and has rounded edges without sharp protrusions.

In addition, pins can be mounted so that they do not stick out from the clamps. Therefore there is no need to use pin caps to protect patients from accidental injuries.

### RADIOTRANSSPARENT TELESCOPIC CENTRAL UNIT

The central unit of the Radiolucent Wrist Fixator is composed of a thin tube sliding into a cylinder. This design makes the central unit telescopic, so from an overall length of 13 cm, it can expand up to 19 cm. Thanks to the telescopic unit, it is possible to perform fracture reduction when pins and fixator have been already mounted [3].



Uncontrolled rotations of the external tube around the cylinder are impeded by a blocking screw.

The internal cylinder is made of PEEK, whereas the external tube is made of aluminum that is only 0.6 mm thick. Material choice and thickness have been optimized to have satisfactory radiotransparency, a feature generally recognized as important for visualization of the fracture site.

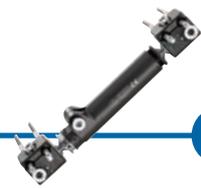


If a unilateral external fixator for distal radius fractures is not radiotransparent, pins need to be placed properly to allow for AP and ML view of the fracture site. If visualization in one plane remains difficult, additional procedures such as placing a dental film between fixator and skin to obtain an unobstructed view [2] or supplementary oblique views, that can be difficult to interpret, need to be performed [4]. The amount of time both surgeons and patients are exposed to X-rays is prolonged and the total operative time increases [4].

Fig. 1: Radiolucent Wrist Fixator radiotransparency

The Radiolucent Wrist Fixator has satisfactory radiotransparency to allow for visualization of fracture reduction and scaphoid and carpal alignment during healing [3] (Fig. 1).

# Radiolucent Wrist Fixator



## LIGHTER THAN OTHER FIXATORS ON THE MARKET

One of the advantages of external fixators for the treatment of wrist fractures in comparison to casts is that they are lighter in weight [5]. It is well-accepted that a lightweight design improves wearing comfort for the patients [6]. The Radiolucent Wrist Fixator is lighter than other external fixators for distal radial fractures on the market (Fig. 2). This results from the low specific gravity materials. Pins and closing mechanisms are made of stainless steel for mechanical and structural reasons.

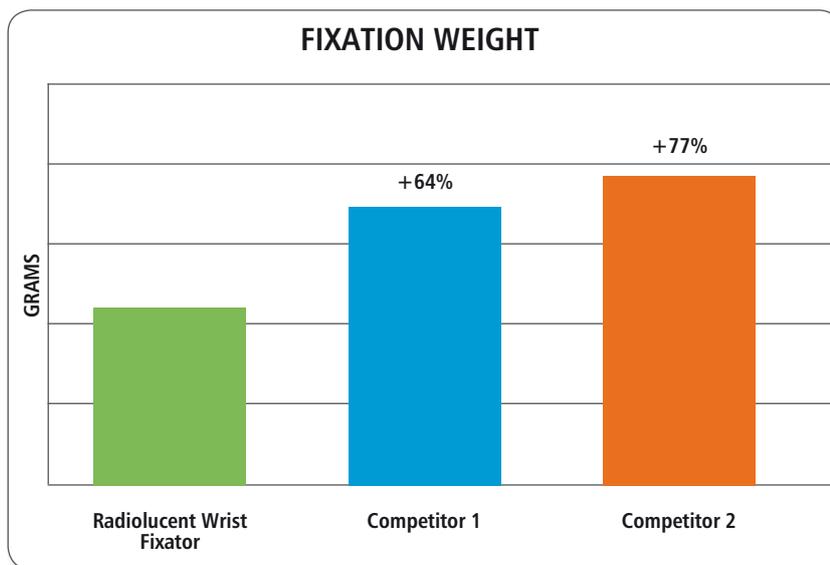


Fig. 2: Radiolucent Wrist Fixation System is lighter than other systems on the market



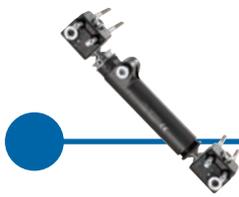
Fig. 3: Compression-distraction unit

The Radiolucent Wrist Fixator has an additional unit which is mounted on the fixator intra-operatively and helps the surgeon to perform compression-distraction (Fig.3). Once the procedure is completed, the compression-distraction device can be removed. This solution permits further reductions in the weight of the fixator.

## DOUBLE BALL-JOINT FOR HIGH MANEUVERABILITY



The Radiolucent Wrist Fixator is composed of two clamps connected to the central unit through a ball-joint. Thanks to this particular feature, it is possible to move the clamp in all axes with a total angulation of up to 64°. This improves maneuverability of the system during fracture reduction.



# Radiolucent Wrist Fixator

## SPECIAL LOCKING CAM FOR HIGH-BALL JOINT LOCKING STRENGTH

In the Radiolucent Wrist Fixator ball-joints are locked by tightening a locking cam characterized by a special geometry (Fig. 4). Its design assures high ball-joint locking strength [internal reports]. This closing mechanism has been designed to reduce the probability of ball-joint locking failure that can lead to loss of stability and consequently loss of reduction.

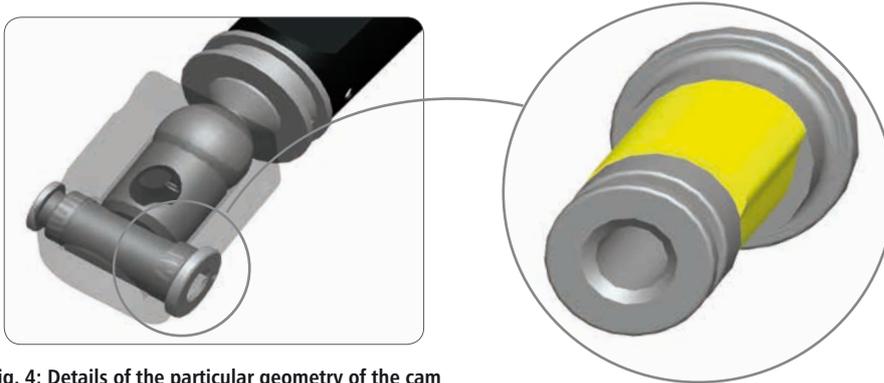


Fig. 4: Details of the particular geometry of the cam

## SPECIAL PIN SET AND DEDICATED INSTRUMENTATION FOR PIN POSITIONING

Anchoring pins used in external fixation, since they are subjected to bending force, should be sufficiently large and strong, but should not exceed a third of the bone diameter to prevent secondary pin hole fractures [7]. In regard to distal radius fractures, the fixator pins should have an adequate size: a 3-3.5 mm diameter combines stable fixation with minimal bone damage and an adequate pin-bone interface [2].

The Radiolucent Wrist Fixation System pins have a standard Orthofix tapered thread design. Before inserting the pin, predrilling is required.

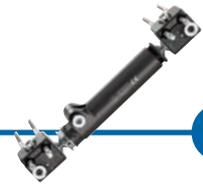
Predrilling of fixator pins has shown to reduce the degree of thermal necrosis, which may contribute to pin loosening [2].



Fig. 5: Screw guide template

The Radiolucent Wrist Fixator is supplied with a special instrumentation for pin positioning. The screw template consists of a fixed screw guide and a threaded screw guide the position of which can be regulated according to the bone anatomy. It has been shown that this instrumentation ensures that the pins are positioned parallel and 14 mm apart, which is the spacing in the fixator pin clamps [3].

# Radiolucent Wrist Fixator

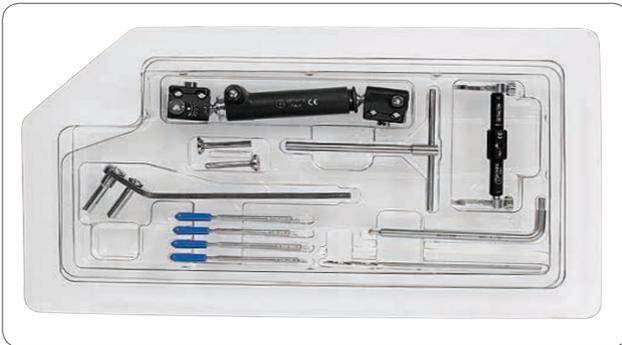


## COMPATIBLE WITH K-WIRE AUGMENTATION

Augmentation of external fixation with K-wires has shown to increase stability of distal radial fractures [7, 8], reduce the need for excessive traction [7, 8] and avoid 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 Radiolucent Wrist Fixator can be successfully used in combination with K-wire fixation [3].

## READY TO BE USED THANKS TO THE STERILE KIT



Thanks to the sterile kit, the Radiolucent Wrist Fixator is ready to be used.

Fig. 6: Sterile kit blister



# Radiolucent Wrist Fixator

## 3. MECHANICAL FEATURES

### HIGH STIFFNESS

It is not known which rigidity is required for adequately stabilizing a distal radius fracture [10]. It is thought that a stiff external fixator promotes primary fracture healing while a less rigid device promotes more of a secondary fracture healing [11]. Rigid external fixators help to obtain and maintain an acceptable reduction until the fracture has gained sufficient stability [7]. In highly unstable fractures, rigid fixation is required to maintain a satisfactory anatomical position [12].

In order to evaluate Radiolucent Wrist Fixator bending stiffness, mechanical tests comparing different external fixators for distal radius fractures were performed.

These tests were performed internally during the development of the device.

### AXIAL, A-P AND M-L BENDING STIFFNESS TESTS

#### Testing Protocol

The fixators were mounted on stainless steel alloy bars and a gap of 20 mm was maintained to present the fracture site. Load was applied, and stiffness values were calculated from the load-deformation curve as reported in [13]. For each test type, fixators were tested in three different configurations:

Configuration 1:  $D = 10$  mm

Configuration 2:  $D = 15$  mm

Configuration 3:  $D = 20$  mm

where  $D$  is the distance between the frame and the bars.

Each configuration was tested 5 times.

#### Results

The results demonstrate that the Radiolucent Wrist Fixator is characterized by high axial, A-P and M-L bending stiffness, comparable to Pennig Dynamic Wrist Fixator and higher than other competitors on the market (Fig. 7, 8 and 9).

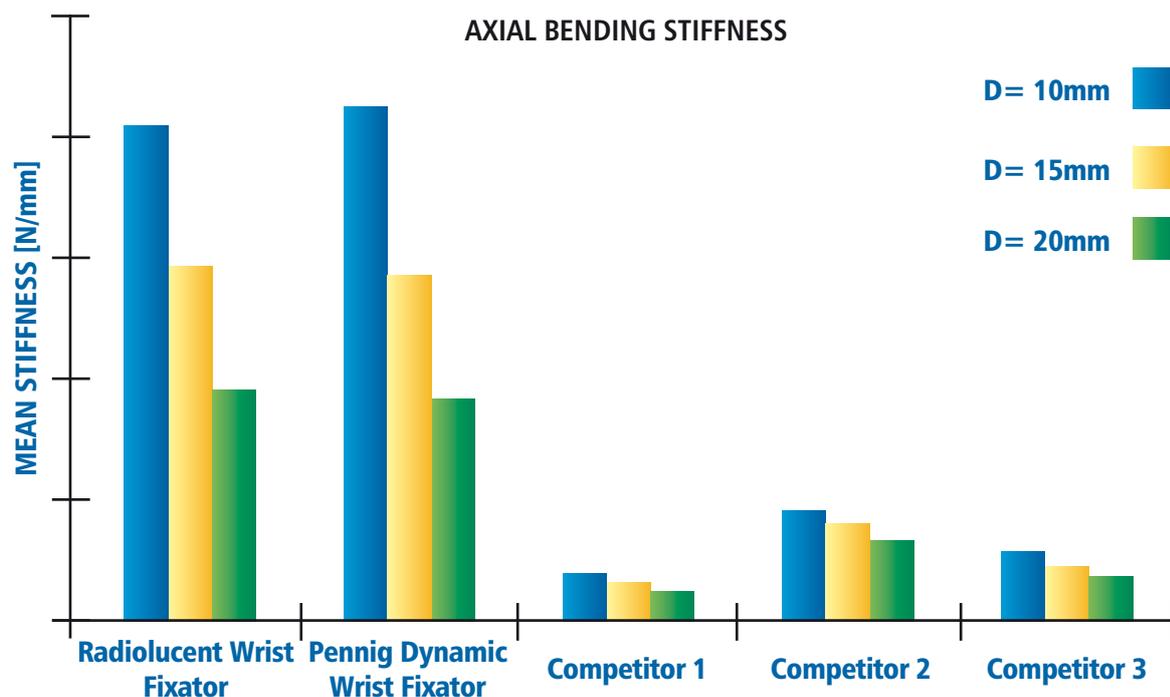


Fig. 7: Axial Bending Stiffness

# Radiolucent Wrist Fixator

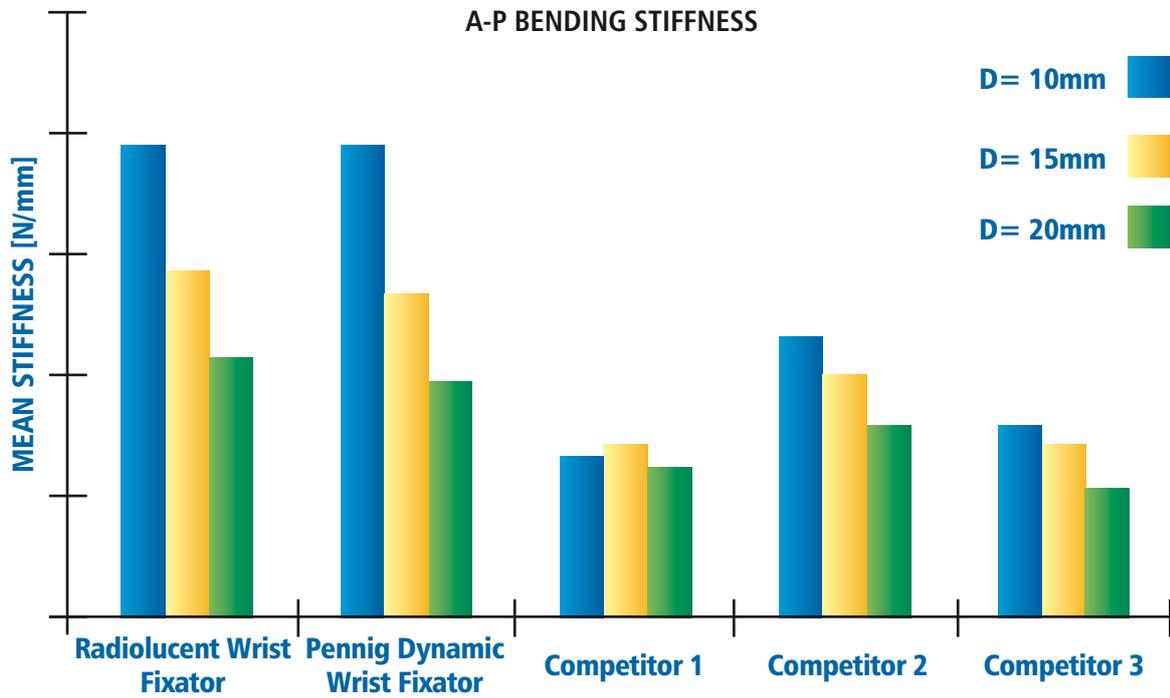
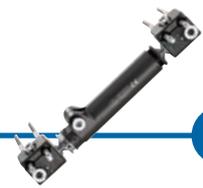


Fig. 8: A-P Bending Stiffness

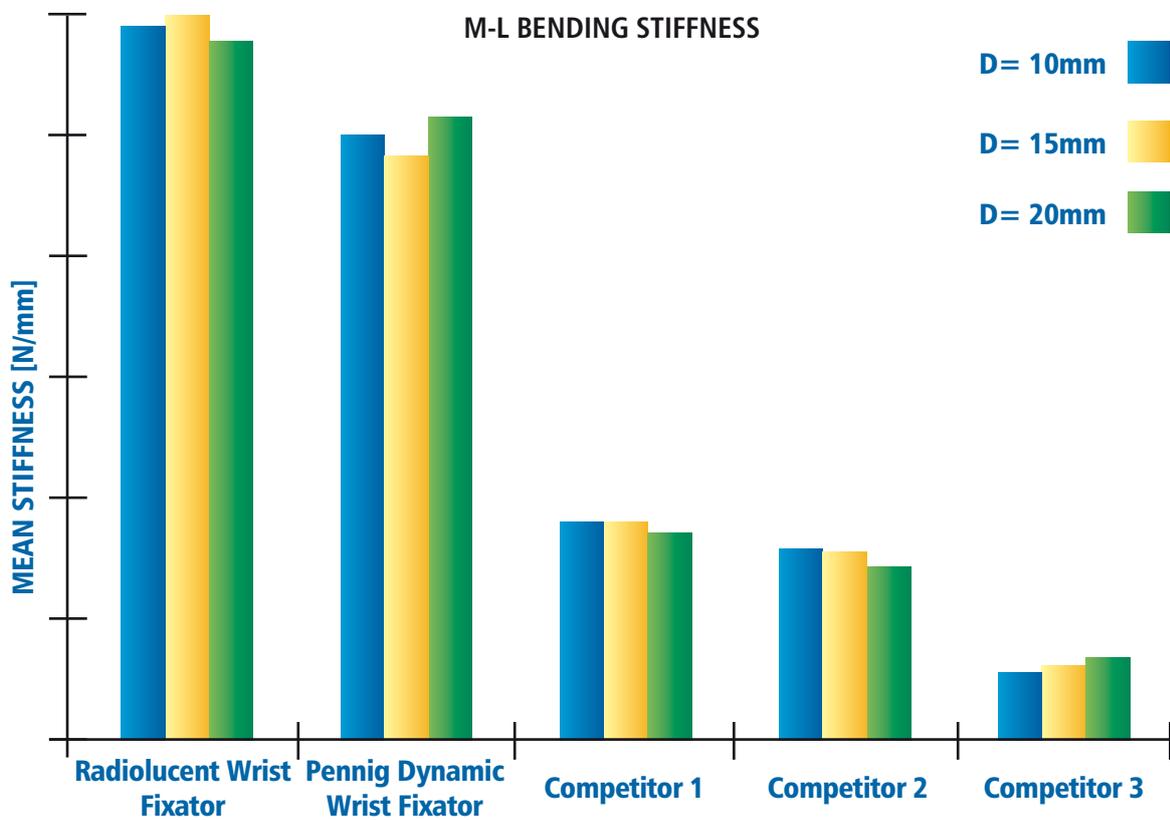


Fig.9: M-L Bending Stiffness



# Radiolucent Wrist Fixator

## 4. CONCLUSIONS

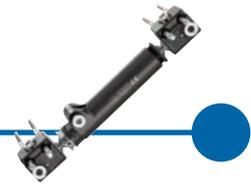
This document was created to give a detailed description of the Radiolucent Wrist Fixator features.

The technical features were studied to provide a simple, low profile, radiolucent and lightweight external fixator. Mechanical tests prove that the Radiolucent Wrist Fixator is characterized by high stiffness comparable to the Pennig Dynamic Wrist Fixator and higher than other external fixators for distal radial fractures on the market.

In conclusion, Radiolucent Wrist Fixator is a simple, but advantageous system for the treatment of fractures of the distal radius.

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