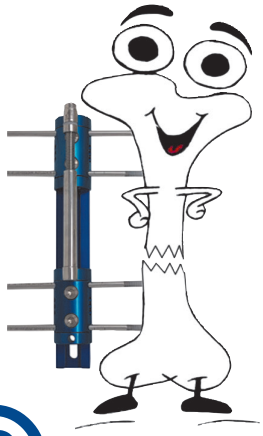
Dial Medicali

MILANO - ITALY



Rail-Fix®

ExFix for the lengthening of long bones

SURGICAL TECHNIQUE

INTRODUCTION

RailFix® is an external fixator composed by rails of different lengths, clamps and distractors. The appropriate assembly of these elements allows to treat the long bones lengthening or transport (“lift technique”).

RailFix® is available both for adult patients’ treatment and pediatric ones. Moreover, having been manufactured with avionic aluminum alloy, it shows an extraordinary sturdiness. The aim of this handbook is to highlight the application procedures without referring to any anatomical, physiological or biological topic.

RailFix® is well known and mainly implanted for the treatment of post traumatic or genetic dysmetria as well as for bone transport for bones loss. Prior adequate surgical assessment, the RailFix® mechanical characteristics its configuration allows to manage linear lenghtening and / or bone transport, if there is in conbination a small deformity is possible adjust it acutely. In case of important monoplanal or multiplanal deformity take into consideration to use circular or hexapodal external frames as RRS/iFixation by Dial Medicali.

The RailFix® system is compatible both with bone-pins with a diameter of 5 mm and bone-pins with a diameter of 6 mm. It is recommended the use of the Dial Medicali PinFix® with hydroxyapatite. Indeed, they are planned in order to transmit a bigger axial elasticity. Furthermore, RailFix® includes an important element – dyna-clamp (spring device for dynamization) – that let to convey axial micromovements during the patient’s walking. It is well known that the axial dynamization is crucial for the bone healing, as a matter of fact.

Depending on the treatment, the adult RailFix® clamp allows the positioning of up to 5 bone-pins (2-3 recommended); the pediatric one up to a maximum of 3 bone-pins. The RailFix® toolkit is simple, user-friendly and composed by few instruments. Nevertheless, it is suggested to utilize it in its entirety and in accordance with this manual. This will allow to prevent unexpected stresses on the bone-pins.

SURGICAL TECHNIQUE

Step 1

Using the appropriate trocar, position the pin-guide on the bone, taking care to be as central as possible with respect to the shaft.

Step 2

Remove the trocar from the pin-guide and insert the right guide-drill (4,5 mm for 6mm diameter pins – 3,2 mm for 5mm diameter pins). If a motor is used, drill the bone at a low number RPM **untill reaching and passing the second cortex**.

Step 3

Insert the chosen pin till reaching the second cortex.

N.B: To assure a greater bearing capacity, it is recommended to tight the pin over the second cortex of 1-2 pin-threads.

SURGICAL TECHNIQUE

Step 4

Assemble on the desired rail the test clamps.

Without removing the pin-guide, open the most proximal test clamp and place in it the previously set pin.

It is advisable to use the most proximal pin housing.

Arrange now, distally, the second test clamp, calculating the right distance for the corticotomy. The optimum range between the proximal/distal screw and the corticotomy point should not be less than 15/20 mm.

Repeat the step 1/3, locating the pin in the most distal pin housing of the test clamp.

Step 5

In order to set the other pins in the remaining clamp holes, repeat the same instructions of the step 1-3. It is suggested to place the pin of the central hole of the clamp only once the others are inserted.

To simplify this operation, it might be useful to cut the other screws.

Step 6

Remove all the system and the pin-guides, by sliding them on the pins. Remove the test clamp and replace it with the final one choosing the appropriate configuration (with 1 or 2 holes). Loosen the bolts of the clamps and place the fixator on the pins.

Make sure to choose the right length of the rail. Utilize a longer one in case of doubt.

NB: it is extremely important to not set the clamps over the rail bounds.

Step 7

Checking the distance between the pins and the point of osteotomy, it is possible now to proceed with the corticotomy.

Once completed, insert the distractor in the appropriate holes. Using the provided Allen key (6mm for the adult system – 5mm for the pediatric system), rotate counterclockwise the distractor and verify, by X-Ray, the complete separation of the cortexes. Every single round of Allen key is equal to 1mm of linear distraction. It is necessary to distract at least 2/4 mm in order to check the complete division of the cortexes.

Reached this point, rotate clockwise the distractor up to reach a good compression between the two bones segments.

This procedure involves the sliding of one of the clamps. Hence, it is fundamental that one clamp is not blocked with the bolt on the rail and that it can move axially.

Once the goal is reached (compression or distraction), it is recommended to tight also this clamp.

Step 8

Once completed the bone lengthening or transport, it is possible to insert this element (dyna-clamp) in direct contact with the clamp. The aim is to transfer the axial load on the dyna-clamp and so permit the dynamization of the newly formed callus.

dyna-clamp to allow the dynamization of the callus

The picture shows an example of femur bone transport.

It should also be noticed the proximal and distal clamps with one housing for the distractor. Instead, the central one has two possible holes. The purpose is to facilitate the connection distractor-clamp in relation to different distance covered during the treatment.

It is also present the dyna-clamp, placed next to the proximal clamp.

GENERAL REMARKS

RailFix® is a modern external fixator specifically designed for bones lengthening and/or transport, in accordance to the callogenesis method. It is composed by a rail of different lengths and dimensions (adult, pediatric), clamps and different distractors.
The clamps are available in two configurations: 1 and 2 housing to get the best choice for distractor connection.
RailFix® is a flexible system and it allows the planning of different configurations. Nevertheless, it should be remembered some tips for a correct treatment:

Perform a complete planning in order to detect the right placement of the fixator and its components (pins, clamps and distractors).

Consider the right distances in relation to the planned treatment. It is recommended to insert 3 pins per clamp, specifically in the hole 1 – 3 – 5 of it.

Choose the right length for the rail and in case of doubt pick the longest one.

It needs to remember that RailFix® is a rigid system and it allows just axial movements. It is advisable place the most distal and proximal pins first to achieve correct orientation of the rail relative to the bone.

Do not implant the clamps beyond the bounds of the rail.

RailFix® provides two kind of clamps: with 1 housing for the distractor; with 2 housings for the distractor. The clamp with 2 housings is longer, so it probably will require the use of a longer rail.

The clamps will have different characteristics in relation to the assembly and the treatment period:

Static Clamp: it represents the blocked clamp, which will not slide. Therefore, its bolt shall be properly tight.

Dynamic Clamp: it represents the sliding clamp, moved by the work of the distractor. Hence, its bolt shall be loosened during the lenghtening phase (usually 0.75-1.0mm per day) and immediately tight after it. In case of bone transport, the dynamic clamp will be the central one.

The multiple housings and lengths ease the assembly phase of the distractor. But the shorter distractor fits better for an axial movement. To satisfy this condition, it is therefore necessary to choose the right implant solution, considering especially also the strength of the femoral muscles.

The use of the dyna-clamp allows to transfer the axial load from the newly callus to this element. Consequently, when necessary, the surgeon must insert the dyna-clamp closed to the existing dynamic clamp. Its metallic non colored face must be adherent to the body of the dynamic clamp.
In order to enable the dynamization, it is necessary to loosen the bolt of the dyna-clamp and the controlled range is about 2/3 mm.

The bolts of the clamps and dyna-clamp are equipped with a washer, which lets an optimal tightening. Please ensure it is present.

COMPONENTS

PRODUCT CODE	DESCRIPTION
COMPONENTS FOR ADULT	
03-600251	RailFix adult rail 210 mm
03-600268	RailFix adult rail 250 mm
03-600008	RailFix adult rail 300 mm
03-600015	RailFix adult rail 350 mm
03-600022	RailFix adult rail 400 mm
03-600039	RailFix adult dynamic clamp 2 holes
03-600046	RailFix adult static clamp 1 hole
03-600312	RailFix adult distractor 70 mm
03-600329	RailFix adult distractor 120 mm
03-600459	RailFix adult distractor 160 mm
03-136415	RailFix adult dyna-clamp
03-600411	RailFix adult test clamp
COMPONENTS FOR PEDIATRICS	
03-600275	RailFix pediatric rail 200 mm
03-600282	RailFix pediatric rail 250 mm
03-600114	RailFix pediatric dynamic clamp 2 holes
03-600121	RailFix pediatric static clamp 1 hole
03-600299	RailFix pediatric distractor 80 mm
03-600305	RailFix pediatric distractor 120 mm
03-136422	RailFix pediatric dyna-clamp
03-600428	RailFix pediatric test clamp

Dial Medicali srl
Viale Berbera 45 - 20162 Milano - Italy
Tel. +39.02.89828078 - Fax +39.02.66104021

REV 00-2021