QUICK REFERENCE GUIDE

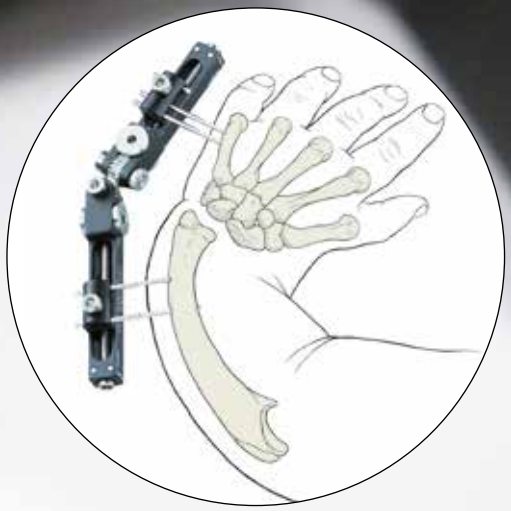
M2

MultiPlanar MiniRail™ System

Correction of Upper Extremity Contractures

MiniRail System

Part C: M2 Multiplanar MiniRail



ORTHOFIX®

M2

MultiPlanar MiniRail™ System

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GENERAL INFORMATION

The M2 is provided as a non-sterile device.

There are a variety of screws available for this device, as listed on the back cover of this guide.

In this technique we use the term screw instead of wire. The screws have 3mm diameter shafts with different sized threaded tips and the wires have 2mm diameter shafts (see table on back page). The threaded wires are more applicable for use in the Radial Club Hand procedures, as the majority of patients are age three years or less and have very small bones.

The largest selected diameter screw should be compatible with the patient's bone diameter. The hole in the bone should not be larger than 30% of the bone diameter, and should be in the center of the bone axis. This is particularly important for stability when lengthening.

All implants are self-drilling. The wires can be inserted directly percutaneously; the screws should be inserted through a small incision.

Because they have different shaft diameters, screws and wires should NEVER be positioned in the same clamp.

PRECAUTION: Any attempt to back out an Orthofix conical screw once it has been inserted may cause it to become loose.

The 1.6 and 2.0mm wires have cylindrical threads, and can be backed out if necessary.

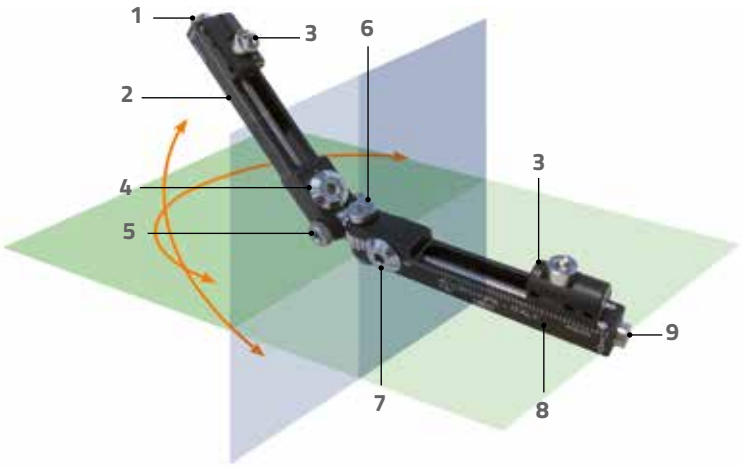
PRECAUTION: Diaphyseal bone screws and wires should always be inserted perpendicular to and in the center of the bone axis to avoid weakening it.

If 2.5 -2.0mm threaded screws are used and need to be backed out, a screw with a larger diameter thread can be inserted.

The MultiPlanar Geared MiniRail M2 permits angular corrections and joint distractions. The device consists of 2 linked monorails connected by paired gears.
It is constructed to allow:

- Geared rails allow gradual positioning in both radio-ulnar or dorso-palmar planes
- Distraction and compression can be accomplished in either railed segment

With complex upper extremity deformities, there is no standard center of rotation or arc of motion for the wrist deformity. Careful monitoring is required by the surgeon for a successful outcome. The center of rotation will change with compression/ distraction, dorso-palmar or radio-ulnar correction. Proper correction and adjustments will be dependent on the age and size of the patient in addition to the specific deformity.

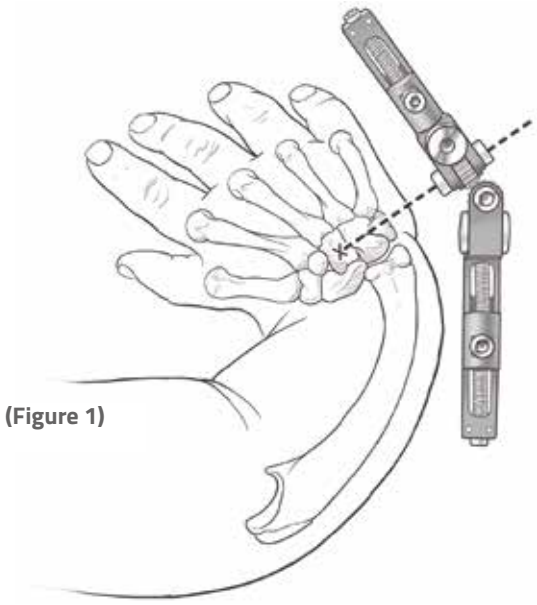


1. dorso-palmar compression/distraction screw
2. dorso-palmar rail
3. screw clamp
4. dorso-palmar flange & socket
5. dorso-palmar locking screw
6. radio-ulnar locking screw
7. radio-ulnar flange & socket
8. radio-ulnar rail
9. radio-ulnar compression/distraction screw

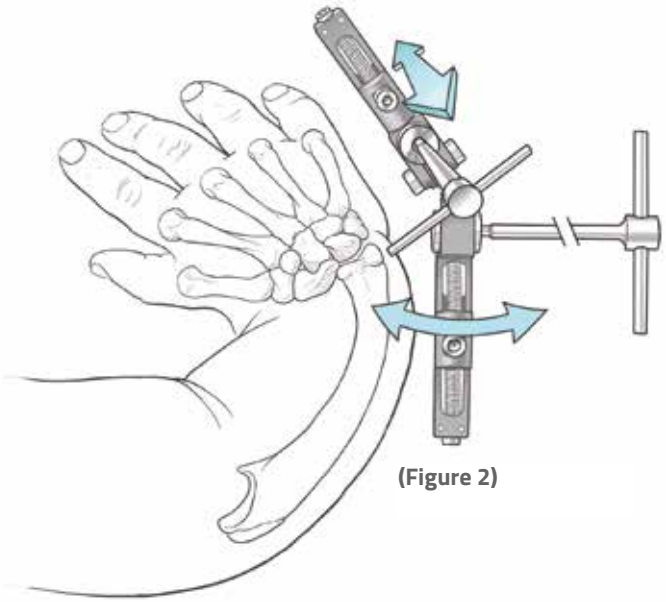
Please kindly refer to the product IFU PQMIN, to the Orthofix implantable devices and related instrument IFU PQSCR, and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

SOFT TISSUE CORRECTION PRIOR TO CENTRALIZATION OR RADIALIZATION

1. Determine the center of rotation of the deformity. Align the M2 dorso-palmar center of rotation at the level of the capitate to serve as a visual reference for determining the first distal screw insertion point. **(Figure 1)**



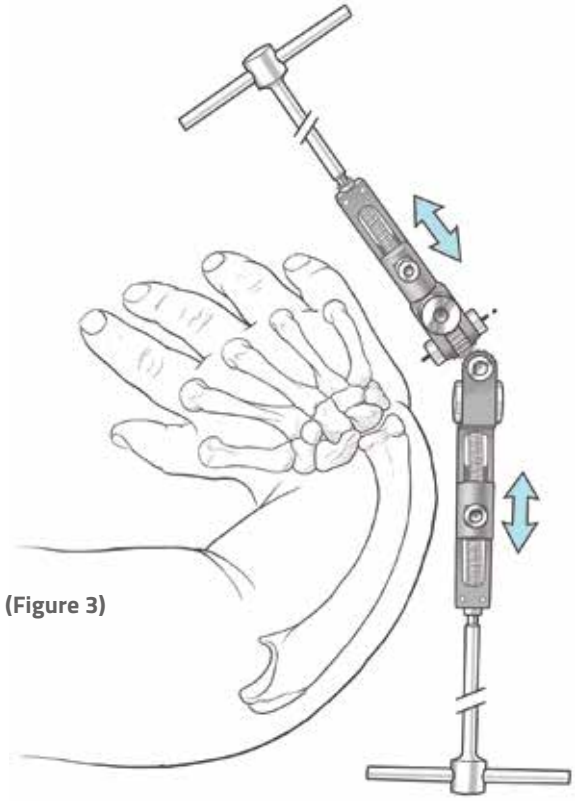
(Figure 1)



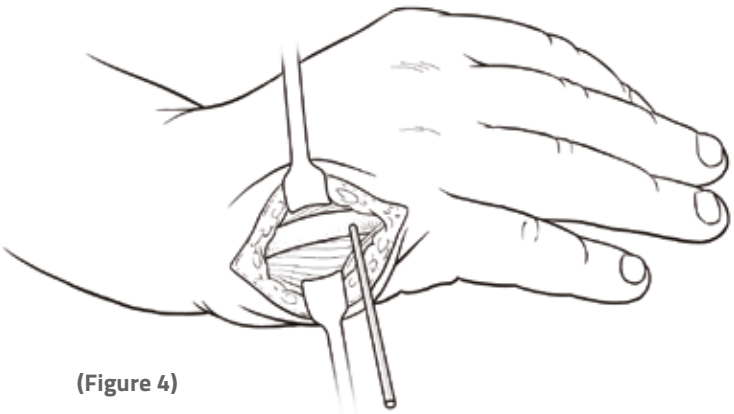
(Figure 2)

2. Position the monorails to match the deformity by using a 3mm wrench to adjust the dorso-palmar and the radio-ulnar links. The adjustment can be refined once the rail is applied to the screws. **(Figure 2)**

3. Ideally, allow space on either side of the screw clamps for subsequent compression and/or distraction.
To move the screw clamps, turn the screw at the end of the rail with a 3mm wrench (clockwise = distraction, counterclockwise = compression) in the end of the rail segments. In small children it may be necessary to maximize compression; i.e. position the clamp as proximal to the gears as possible on the distal rail to align the radio-ulnar axis with the gear. Although not ideal, if the 5th metacarpal is too short, placing a screw in the 4th will allow more room for the distal rail. **(Figure 3)**



(Figure 3)



(Figure 4)

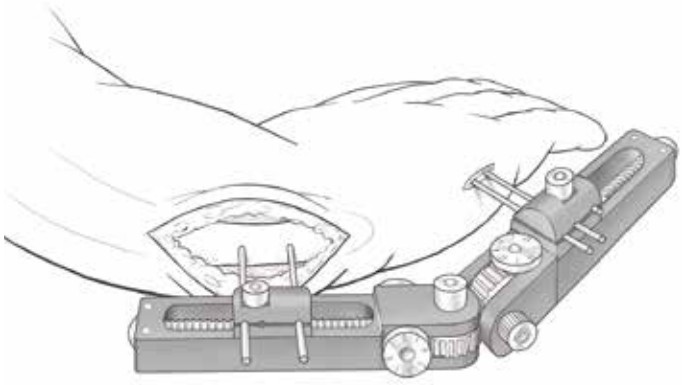
5. Apply the M2 MiniRail over the screw in the outermost seat of the clamp. Insert the second screw, using the clamp as a guide to ensure it is correctly spaced and parallel to the first.

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage. Do not penetrate the entry cortex with the smooth shank to avoid damage to the bone.

PRECAUTION: Any attempt to back out an Orthofix conical screw once it has been inserted may cause it to become loose.

Once both screws are inserted, tighten the screw clamp with a 3mm wrench. **(Figure 5)**

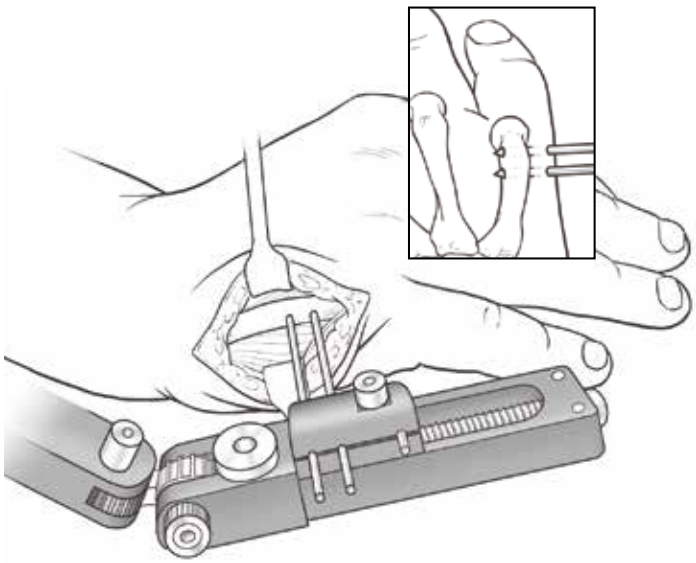
In small children it may be necessary to insert the screws in the two screw seats closest to the gears. A blank screw in the outermost seat is then required to ensure that the screws are all secured evenly. Where there is sufficient room, use the two outermost screw seats for greater stability.



(Figure 6)

4. Make a longitudinal incision over the 5th metacarpal at the proposed position of the screws to expose the bone subperiosteally, thereby protecting neurovascular structures. Insert the first threaded wire or screw in the frontal plane of the metacarpal, at 90° to the long axis of the bone. **(Figure 4)**

The size of screw or wire used will be dependent on patient size. See General Comments for more information.



(Figure 5)

6. Using the M2 as a guide, determine the position of the proximal screw clamp over the ulna. Make a longitudinal incision over the ulnar border, and expose the ulna subperiosteally. Insert the two proximal screws with the same procedure as for the distal screws using the outermost clamp seats, parallel to each other and in the frontal plane at 90° to the axis of the long bone. Once both screws are inserted, tighten the screw clamp with a 3mm wrench. **(Figure 6)**

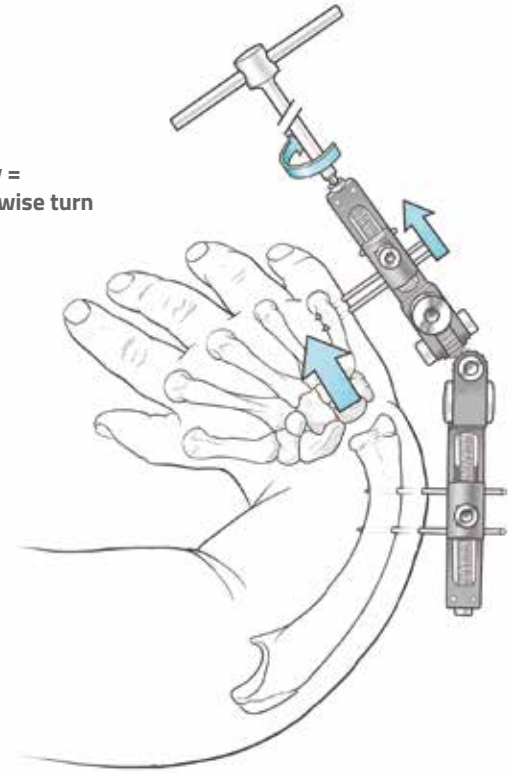
7. Ensure that all screws engage both bone cortices, with 1-2 threads protruding beyond the second cortex.

PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.

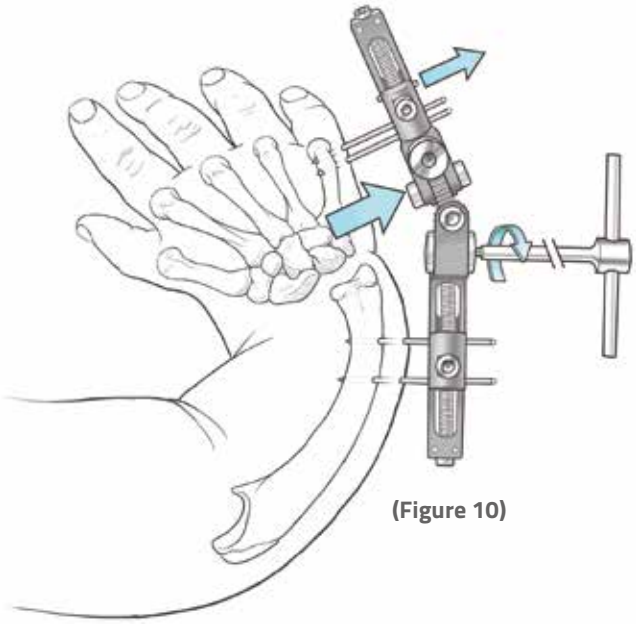
POST OPERATIVE MANAGEMENT

8. The patient should be seen in the outpatients' department on the first post-operative day. Distraction of the hand begins the first day after surgery. The family will be instructed on where and how to turn the gears on the M2 for compression/distraction, dorso-palmar and radio-ulnar corrections. The patient will be seen in the surgeon's clinic once or twice a week for the clinician to monitor the corrections and make adjustments where appropriate.

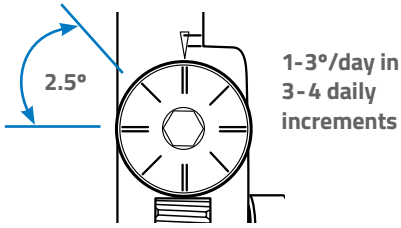
9. Distract at a rate of 1mm per day, using the distal rail, with one quarter turn of the compression-distraction screw, clockwise four times a day. Approximately 2-5mm of total distraction should be sufficient. **(Figure 9)**



(Figure 9)



(Figure 10)

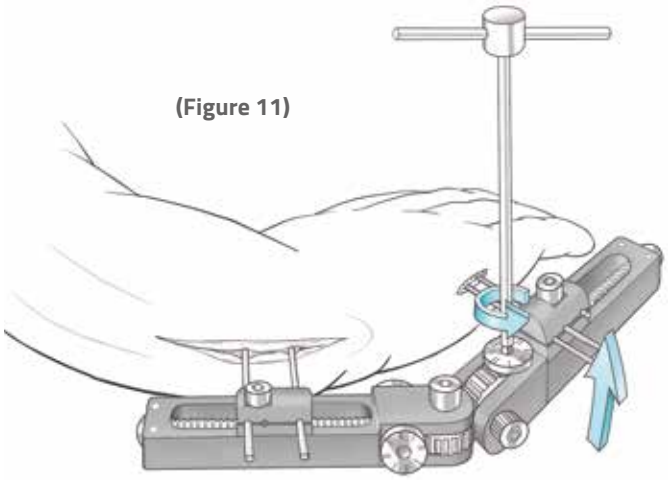


1mark = 2.5° arc

10. Correction is in an ulnar direction, 1-3° daily in 3 or 4 increments, using the radio-ulnar flange. Each mark of the flange represents 2.5°. Speed of correction depends upon the "stiffness" of the tissue and should be patient specific. During the ulnar correction, additional joint distraction of 2-4mm or more may be required to avoid impingement. Following distraction, compression of 1-2mm or more may be required. The axis of rotation may change as ulnar correction takes place, and lengthening may occur. It will be necessary to use compression and/or distraction to maintain the correct center of rotation. **(Figure 10)**

With ulnar fixator placement, ulnar correction of a radial deformity will produce lengthening across the wrist. Appropriate shortening of the rails is necessary to prevent over-distraction.

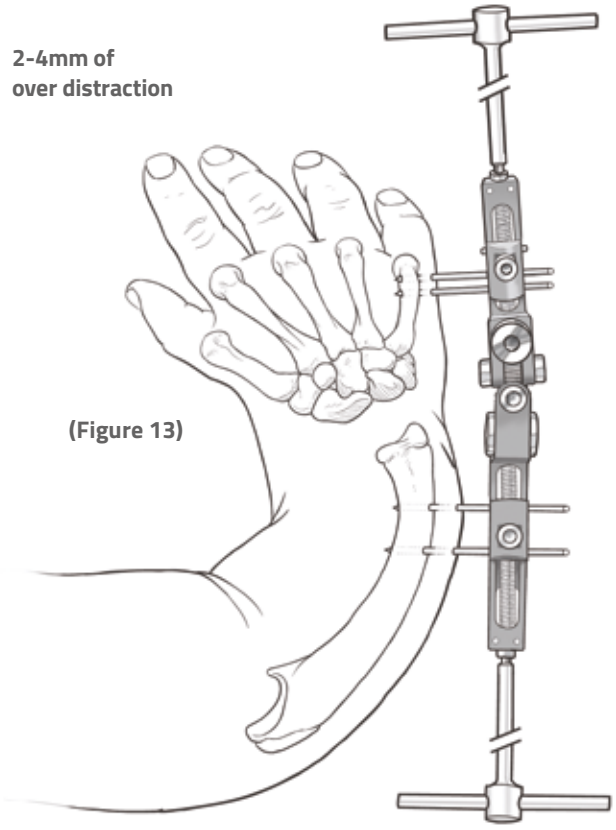
(Figure 11)



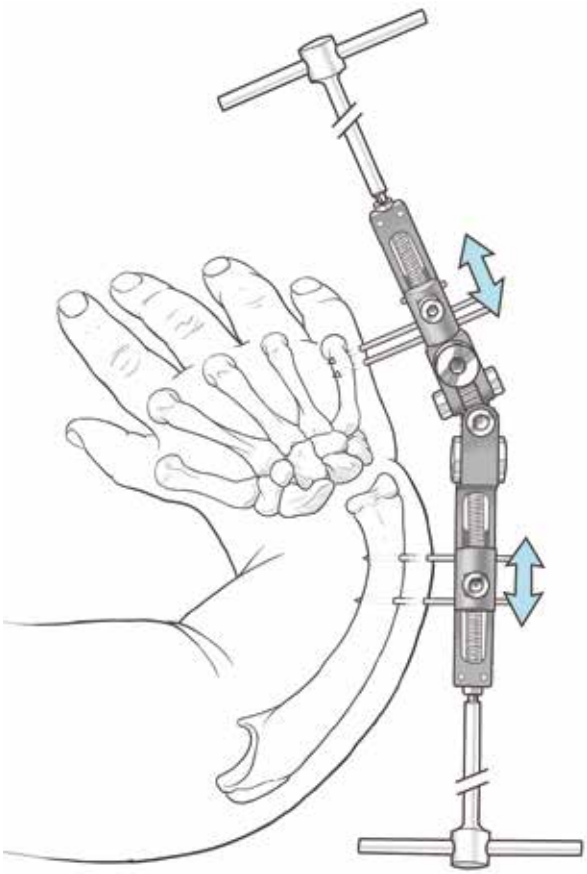
12. The fixator is applied in radial deviation to match the deformity. As correction continues in an ulnar direction, the distance between the distal ulna and proximal carpal bones will depend on the center of rotation of the fixator relative to the ulna. If the position of the center of rotation requires adjustment during correction, the rails move proximally or distally. **(Figure 12)**

2-4mm of over distraction

(Figure 13)



11. Dorso-palmar correction can be accomplished, if necessary, at 1°-3° per day, incrementally, using the dorso-palmar flange. **(Figure 11)**



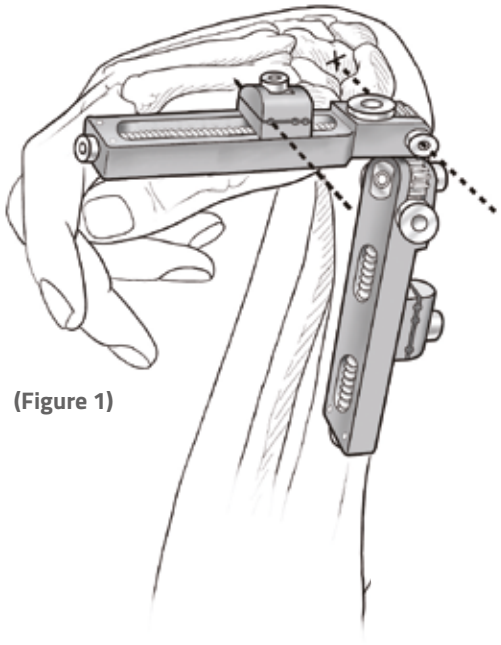
(Figure 12)

13. Continue the correction process until there is 2-4mm of distraction at the wrist joint and radio-ulnar alignment is appropriate. **(Figure 13)**

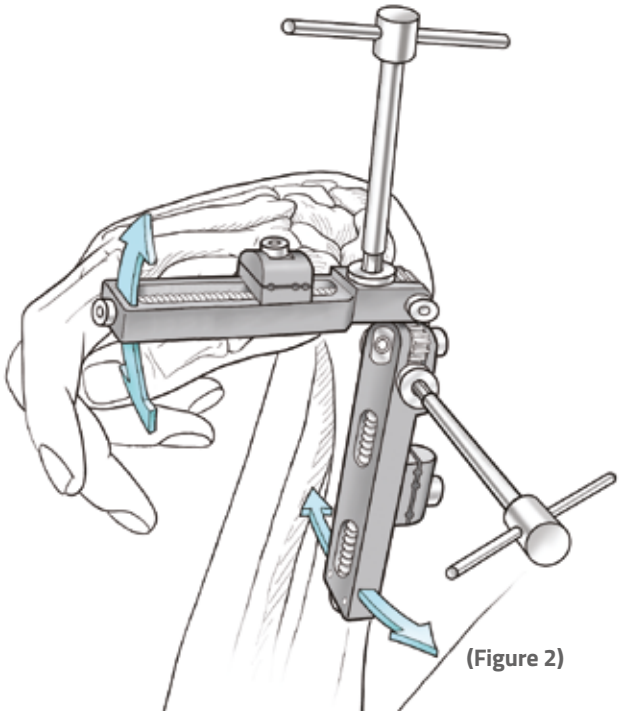
14. For final alignment the hand may need to be shifted in a radial or ulnar direction; this can be achieved by loosening the distal clamp and translating the hand as required. Ulnar osteotomy may also require consideration.

CORRECTION OF WRIST CONTRACTURE SECONDARY TO SPASTICITY

1. Determine the center of rotation of the deformity. Align the M2 dorso-palmar center of rotation at the level of the radial styloid to serve as a visual reference to determine the first distal screw insertion point. **(Figure 1)**



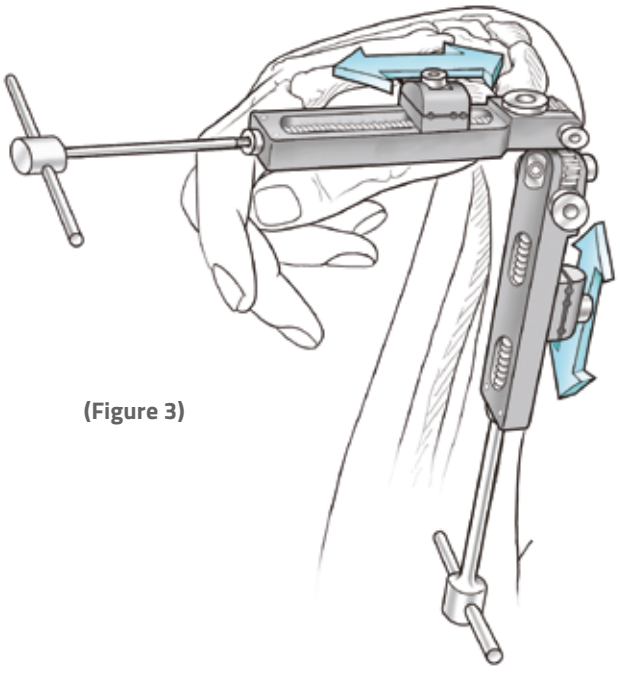
(Figure 1)



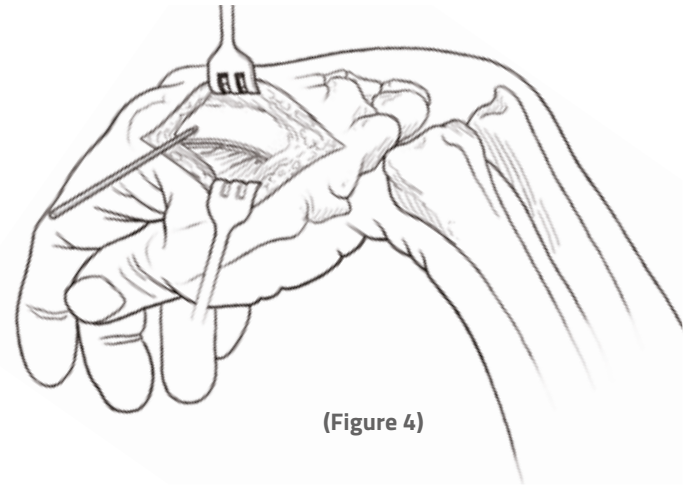
(Figure 2)

2. Manipulate the rails to match the required position of correction, using a 3mm wrench to adjust the dorso-palmar and the radio-ulnar links. The gross adjustment can be refined after the fixator is mounted. **(Figure 2)**

3. Ideally, allow space on either side of the screw clamps for subsequent compression and/or distraction. Equal availability of compression and distraction in both rails is optimal. To move the screw clamps, use a 3mm wrench in the compression/ distraction screw at the end of the rail segments. **(Figure 3)**



(Figure 3)



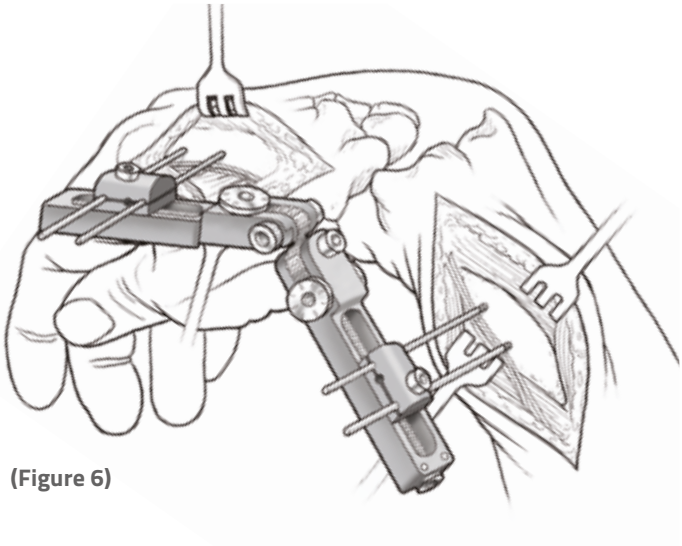
(Figure 4)

5. Apply the M2 MiniRail over the screw in an outermost seat of the clamp. Insert the second screw, using the clamp as a guide, ensuring that the screw is properly spaced and parallel to the first. The screw is positioned either in the base of the 2nd or the 2nd and 3rd metacarpals, capturing 3 or 4 cortices as necessary to obtain good bone purchase.

WARNING: Do not excessively penetrate the second cortex with any type of screws to avoid soft tissue damage. Do not penetrate the entry cortex with the smooth shank to avoid damage to the bone.

PRECAUTION: Any attempt to back out an Orthofix conical screw once it has been inserted may cause it to become loose.

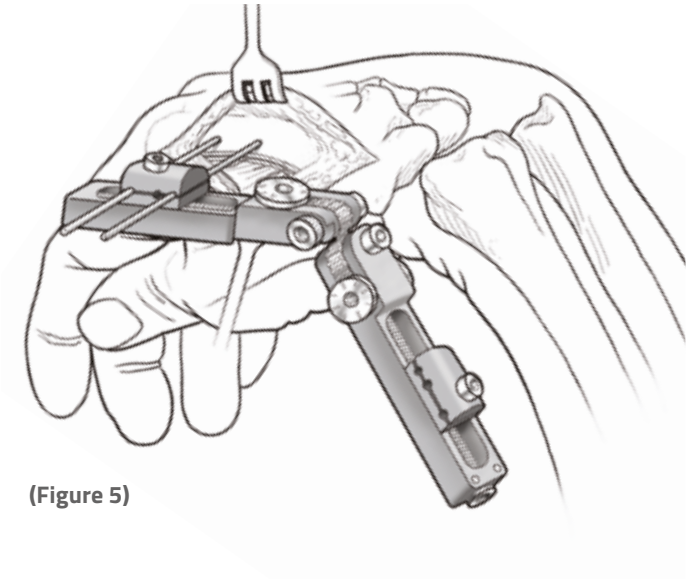
With both screws inserted, the clamp locking screw is tightened with a 3mm wrench. **(Figure 5)**



(Figure 6)

4. Make a longitudinal incision over the central axis of the 2nd metacarpal at the proposed position of the screw, on the radial side and in the frontal plane, and expose the bone subperiosteally. Insert the first 3mm screw in the frontal plane, at 90° to the long axis of the bone. **(Figure 4)**

Whether wires or screws are chosen will depend on the size of the patient. See General Comments for more information.

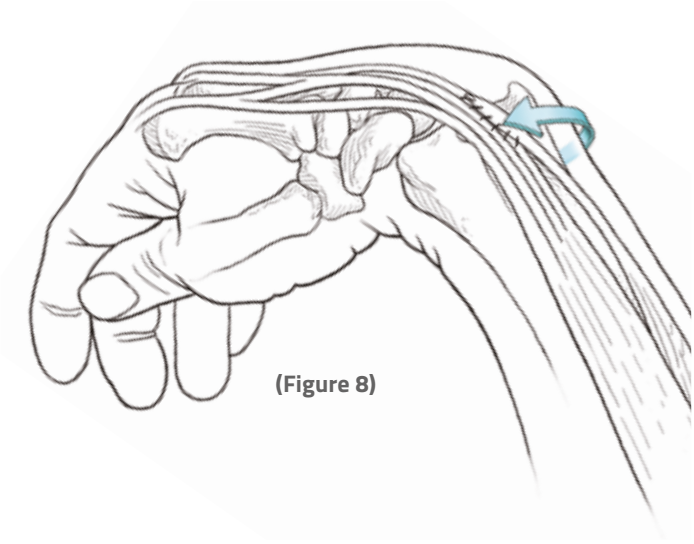


(Figure 5)

6. Using the M2 as a guide, determine the position of the proximal screw clamp over the radius. Prior to proximal screw placement, the superficial radial nerve must be identified and protected. This may be accomplished either by blunt dissection down to the bone and insertion of pin guides or by open incision, retraction of the nerve and insertion of the screw under direct vision. Insert the two proximal screws with the same procedure as for the distal screws, using the outermost clamp seats, parallel to each other, and in the frontal plane at 90° to the axis of the long bone. Once both screws are inserted, tighten the screw clamp with a 3mm wrench. **(Figure 6)**

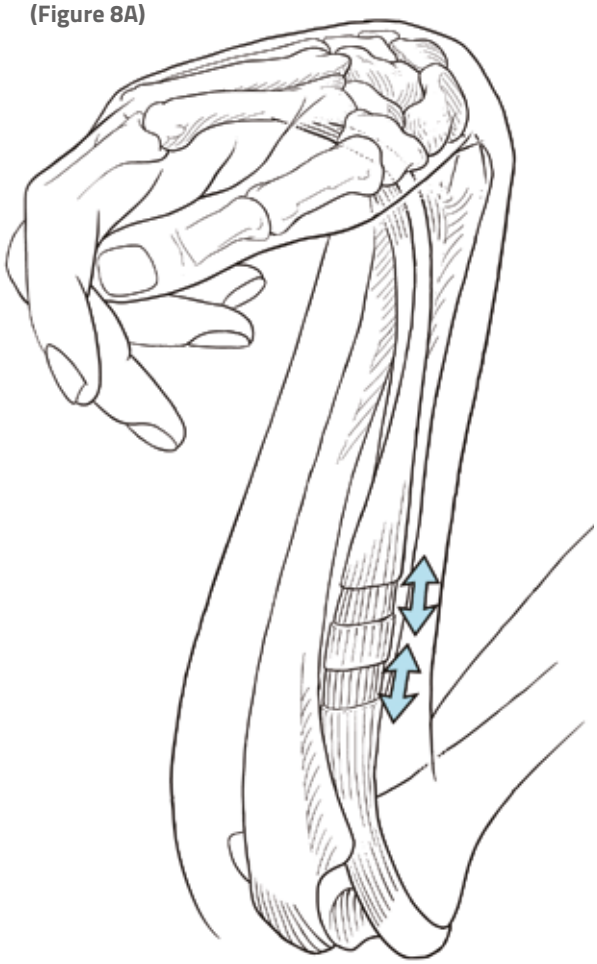
7. Ensure that all screws engage both bone cortices, with 1-2 threads protruding beyond the second cortex.

PRECAUTION: During and after insertion, ensure correct positioning of the implants under image intensification.



(Figure 8)

(Figure 8A)



8. Tendon release is performed as necessary, and it may be easier while doing this to remove the fixator, leaving the screws in place. Options for tendon release include:

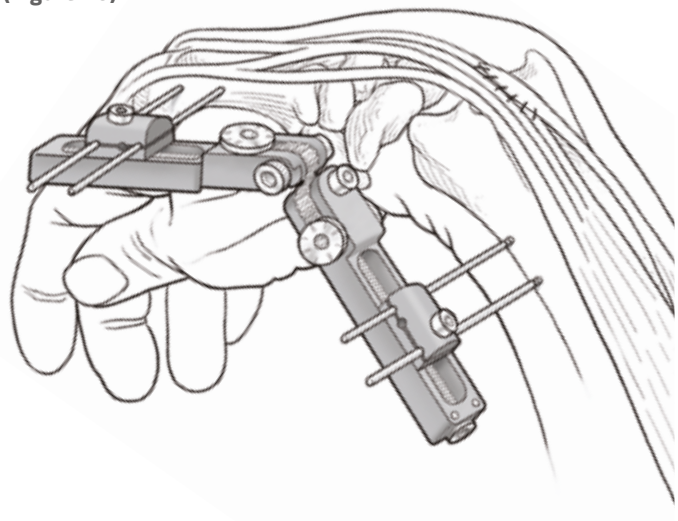
   - Flexor carpi ulnaris (FCU) is lengthened or transferred to extensor digitorum communis (EDC) or extensor carpi radialis brevis (ECRB). **(Figure 8)**
   - The flexor carpi radialis (FCR) is fractionally lengthened. **(Figure 8A)**
   - Chemical denervation may be preformed on flexor carpi radialis (FCR), flexor digitorum superficialis (FDS), flexor digitorum profundus (FDP), and flexor pollicis longus (FPL) to aid correction and decrease muscle pain.

Additional staged tendon release procedures are usually required in the correction phase. The description of these procedures is beyond the scope of this manual. They should be carried out according to best practice as defined in the medical literature.

9. Proximal row carpectomy may be necessary to correct severe fixed deformity.

10. Replace the M2 over the four previously inserted screws as necessary, and tighten the clamps with a 3mm wrench. **(Figure 10)**

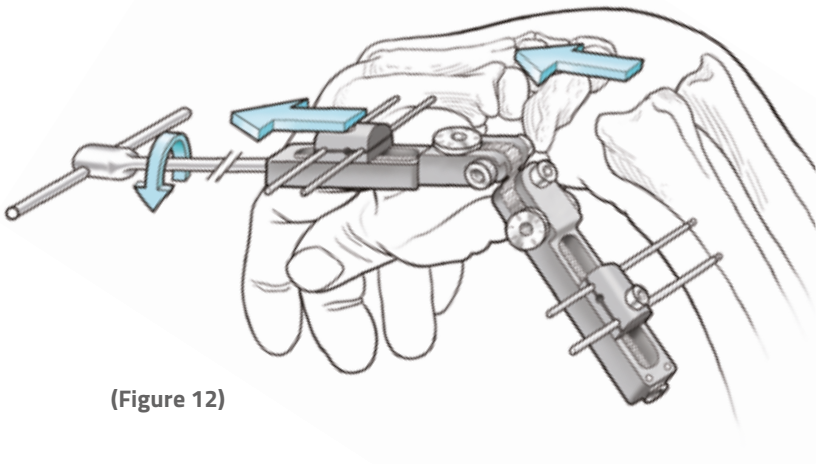
(Figure 10)



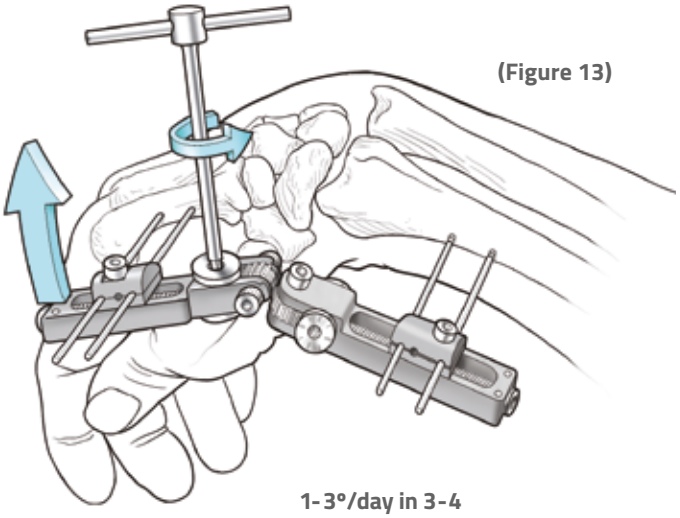
POST OPERATIVE MANAGEMENT

11. The patient is discharged and seen in clinic on the first post-operative day. The family will be instructed on where, when and how to turn the gears on the M2 for compression/distraction, dorso-palmar and radio-ulnar corrections. The patient will be seen in clinic once or twice a week for the clinician to monitor the corrections and make adjustments where appropriate. Careful monitoring is crucial. Fixator adjustments are specific to the patient and the severity of the deformity.

12. Longitudinal distraction may be required, at a rate of 1mm per day, which is accomplished with a one quarter clockwise turn of the distal rail compression/distraction screw, four times a day, producing in all 4-5mm of total distraction. Depending on the stiffness of the soft tissue it may be necessary to alternate distraction and then compression for the comfort of the patient. **(Figure 12)**



(Figure 12)



(Figure 13)

1-3°/day in 3-4 increments daily

13. The hand and wrist should be gradually extended at 1-3° per day in 3 to 4 increments, using the dorso-palmar flange. Passive and active motion of the digits through therapy is encouraged. **(Figure 13)**

ORDERING INFORMATION

M511	M2 MultiPlanar MiniRail Fixator
10012	Allen Wrench 3mm
13570	T-Wrench for Clamp Screws
M210	T-Wrench for Bone Screws
M442	Threaded Wire Extractor
M211	Driver
M225	Template Kit (4 x 1371501 Wire; 4 x 600070 Wire Guide; 4 x 600071 Pin Guide)

Self-Drilling Cortical Screws
3.0 - 2.5mm Thread Diameter / Shaft Diameter 3mm

Thread Length (mm)		18	20	25	30
Total Length (mm)	50	M310			
	60		M311	M312	M313
	70		M314	M315	M316
	100				M317

Self-Drilling Cortical Screws
2.5 - 2.0mm Thread Diameter / Shaft Diameter 3mm

Thread Length (mm)		15	20
Total Length (mm)	40	M300	
	45		M301

Threaded Wires (pack of 4)
Thread Length 15mm / Shaft Diameter 2mm

Thread Length (mm)		1.6	2.0
Total Length (mm)	70	M420	
	100		M426

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.

Electronic Instructions for use available at the website http://ifu.orthofix.it

Electronic Instructions for use - Minimum requirements for consultation:
- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days):
tel +39 045 6719301, fax +39 045 6719370,
e-mail: customerservice@orthofix.it

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.

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