

Correction of Upper Extremity Contractures

MiniRail System

Part C: M2 MultiPlanar MiniRail

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GENERAL INFORMATION:

The M2 is provided as a non-sterile device (see page 11 for cleaning and sterilization instructions).

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

Note: In this technique we use the term screw instead of wire. The screws have 3 mm diameter shafts with different sized threaded tips and the wires have 2 mm 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.

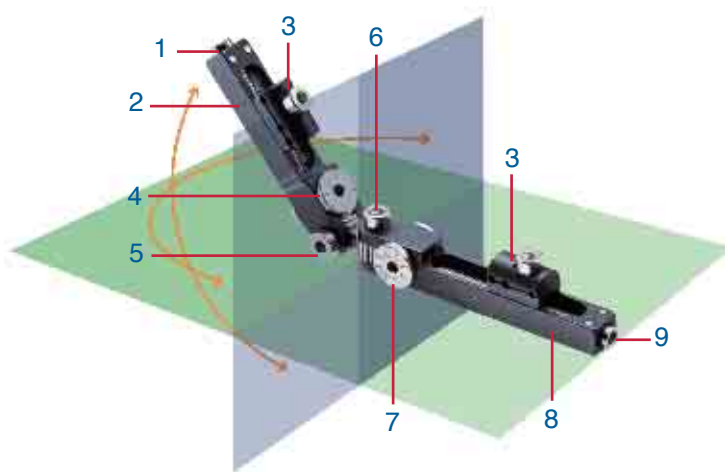
The largest selected diameter screw should be compatible with the patient's bone diameter. The hole in the bone should not be larger than 30% of the bone diameter, and should be in the center of the bone axis. This is particularly important for stability when lengthening.

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

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

All the screws have tapered threads. Care should be taken not to insert them too far. They should **not** be backed out, as loosening will occur.

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



In the diaphysis, screw or wire insertion should be in the center of the bone axis, to avoid weakening the bone.

Note: If 2.5 -2.0 mm threaded screws are used and require to be backed out; a screw with a larger diameter thread can be inserted.

The MultiPlanar Geared MiniRail M2 permits staged correction of complex joint deformities and nonsurgical lengthening of musculotendinous contractures. The device consists of 2 linked monorails connected by paired gears. It is constructed to allow positioning of radio-ulnar or dorso-palmar gears over the center of rotation of the deformity and permits distraction and/or compression by 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.

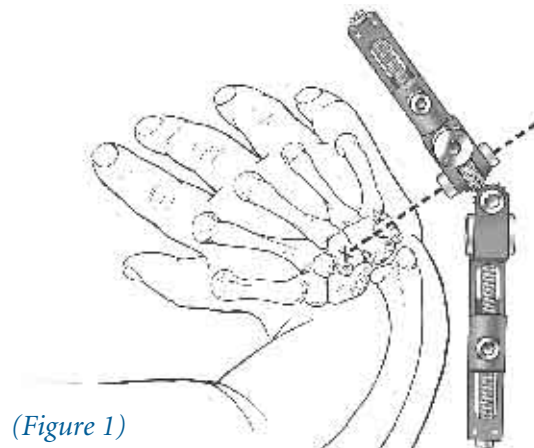
The Indications for the M2 are:

- Complex Upper Extremity Deformities
- Hand Contractures
- Wrist Contractures
- Indicated for Paediatric and Adult patients

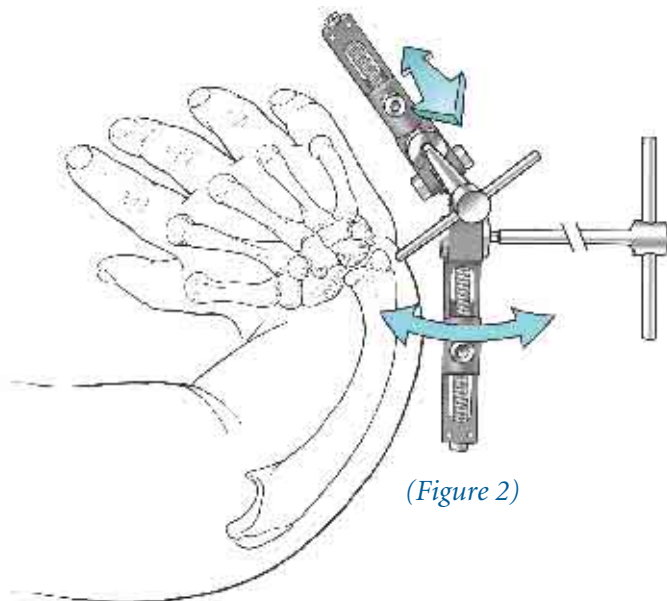
1. dorso-palmar compression/distracton screw
2. dorso-palmar rail
3. screw clamp
4. dorso-palmar flange & socket
5. dorso-palmar locking screw
6. radio-ulnar locking screw
7. radio-ulnar flange & socket
8. radio-ulnar rail
9. radio-ulnar compression/distracton screw

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)



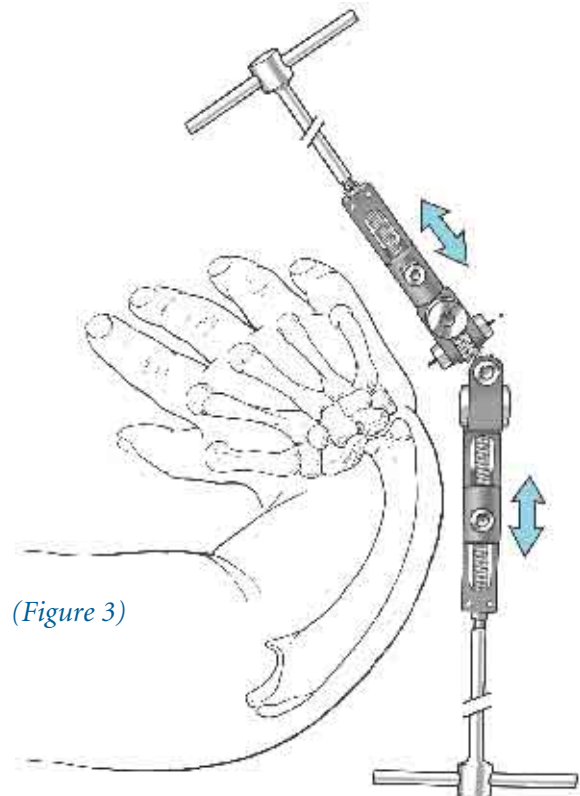
(Figure 1)



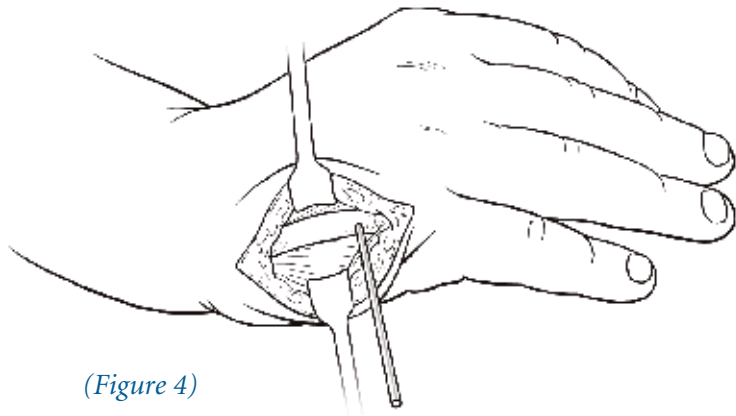
(Figure 2)

2. Position the monorails to match the deformity by using a 3 mm 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 3 mm 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)



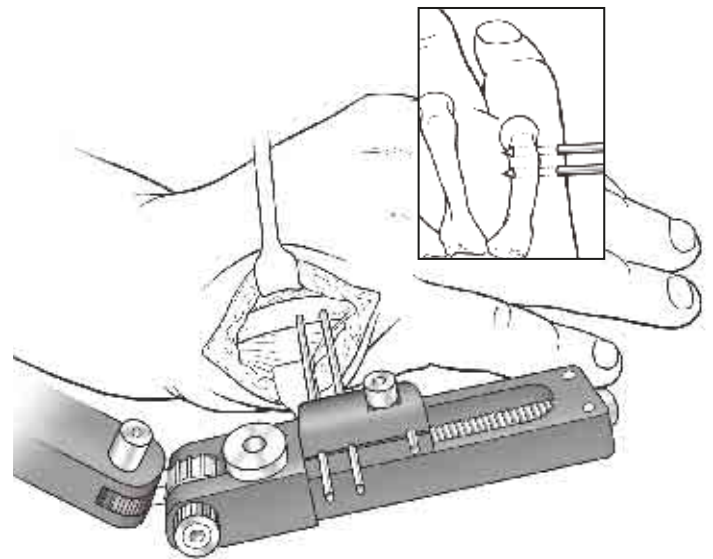
(Figure 4)

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)

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

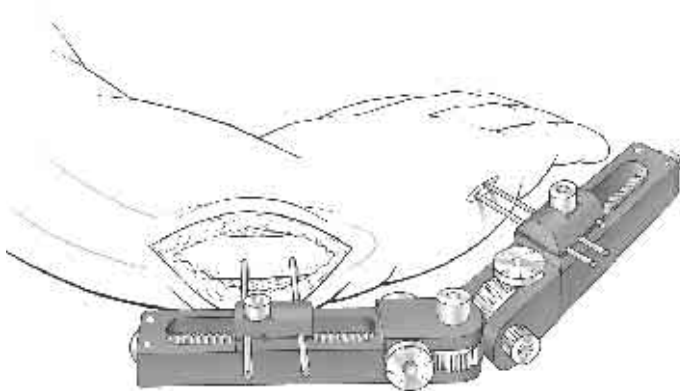
5. Apply the M2 MiniRail over the screw in the outermost seat of the clamp. Insert the second screw, using the clamp as a guide to ensure it is correctly spaced and parallel to the first. Only 1-2 mm of the screw tip should penetrate the second cortex in order to avoid the risk of damage to the soft tissues. Due to the tapered design, conical screws should not be advanced too far, as they will become loose if they are backed out. Once both screws are inserted, tighten the screw clamp with a 3mm wrench. (Figure 5)

Note: 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 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)



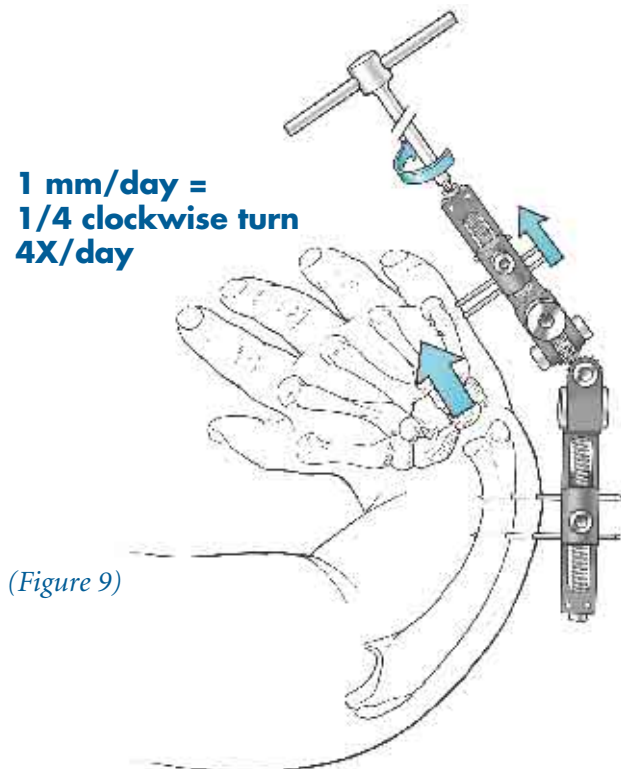
(Figure 6)

7. Confirm accurate position of the screws with an Image Intensifier. Ensure that all screws engage both bone cortices, with 1-2 threads protruding beyond the second cortex.

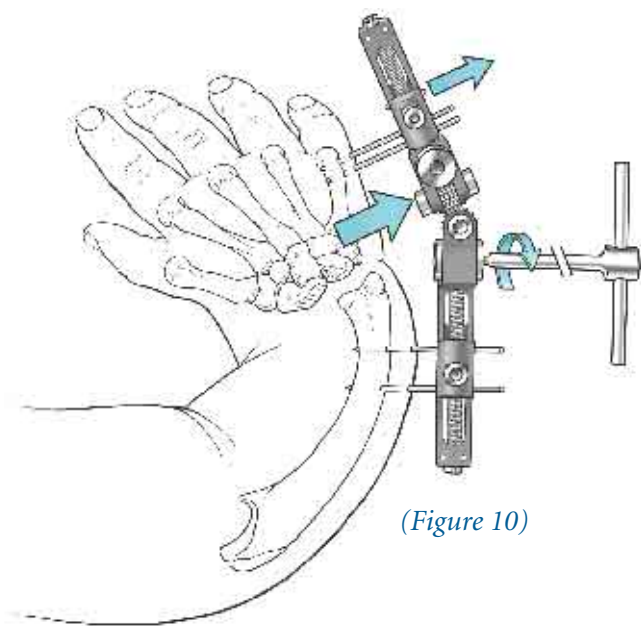
POST OPERATIVE MANAGEMENT

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

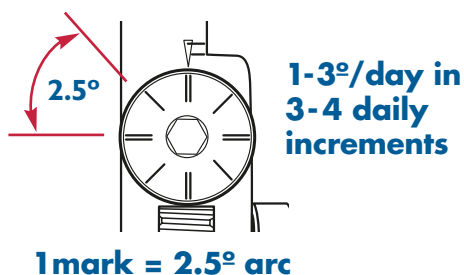


(Figure 9)

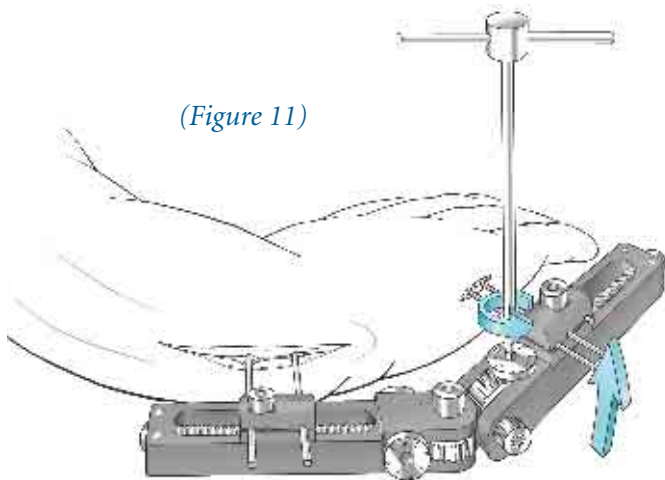


(Figure 10)

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 2-4 mm or more may be required to avoid impingement. Following distraction, compression of 1-2 mm 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)



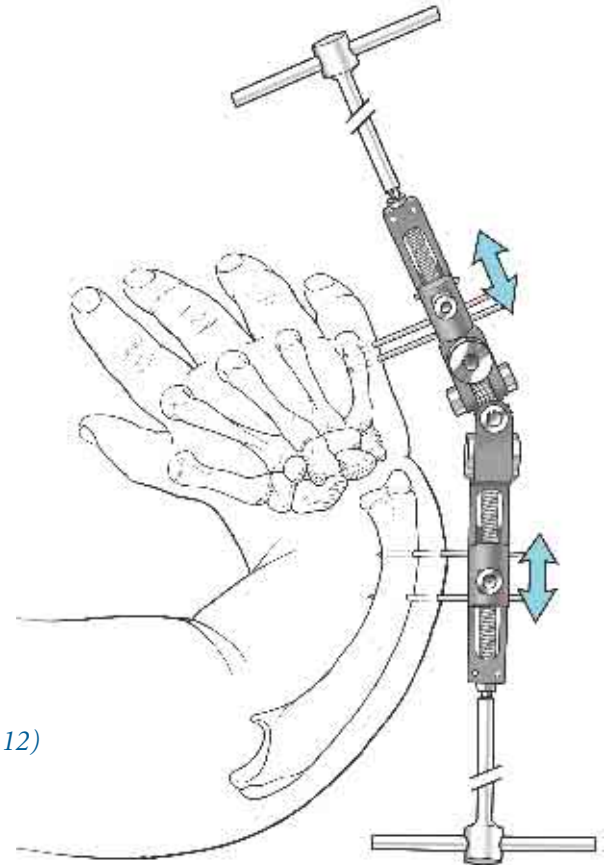
Note: With ulnar fixator placement, ulnar correction of a radial deformity will produce lengthening across the wrist. Appropriate shortening of the rails is necessary to prevent over-distraction.



(Figure 11)

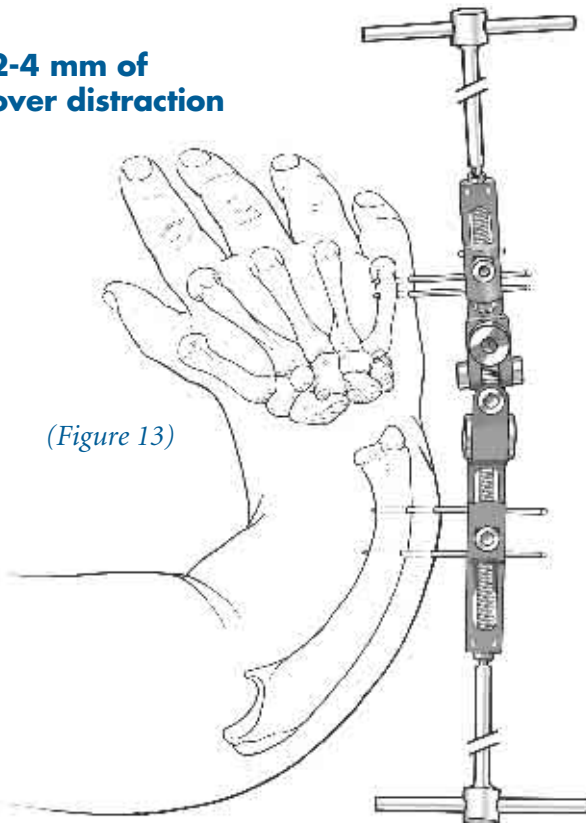
11. Dorso-palmar correction can be accomplished, if necessary, at 1° - 3° per day, incrementally, using the dorso-palmar flange. (Figure 11)

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 are move proximally or distally. (Figure 12)



(Figure 12)

2-4 mm of over distraction

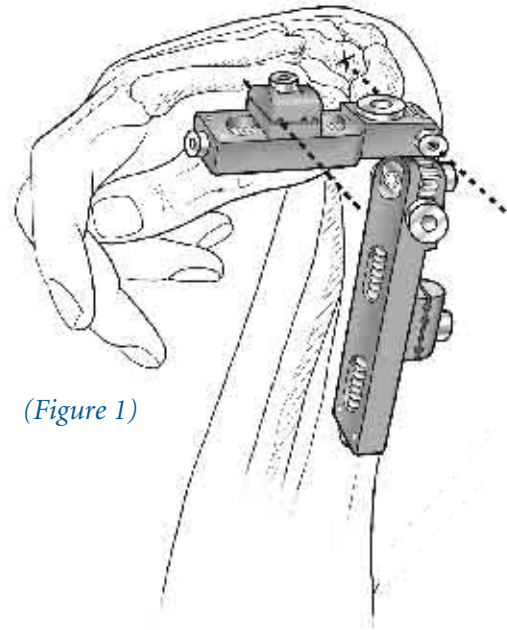


(Figure 13)

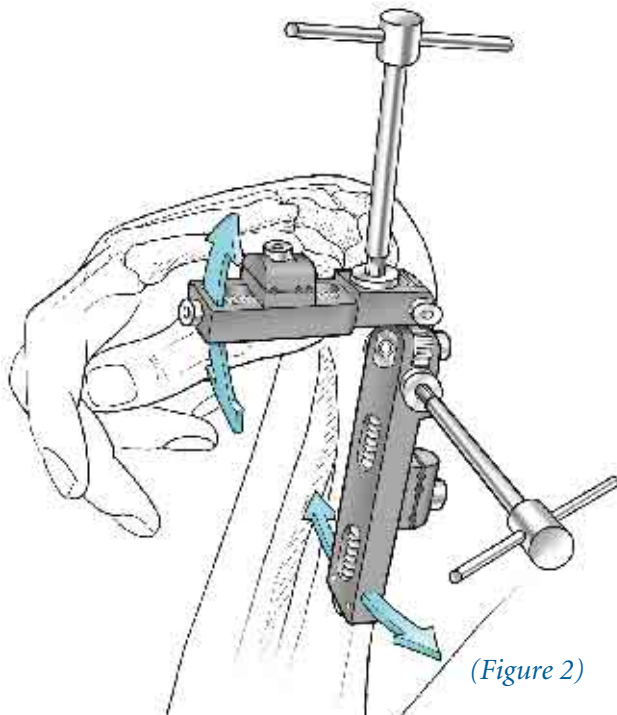
13. Continue the correction process until there is 2-4 mm of distraction at the wrist joint and radio-ulnar alignment is appropriate. (Figure 13)
14. For final alignment the hand may need to be shifted in a radial or ulnar direction; this can be achieved by loosening the distal clamp and translating 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)



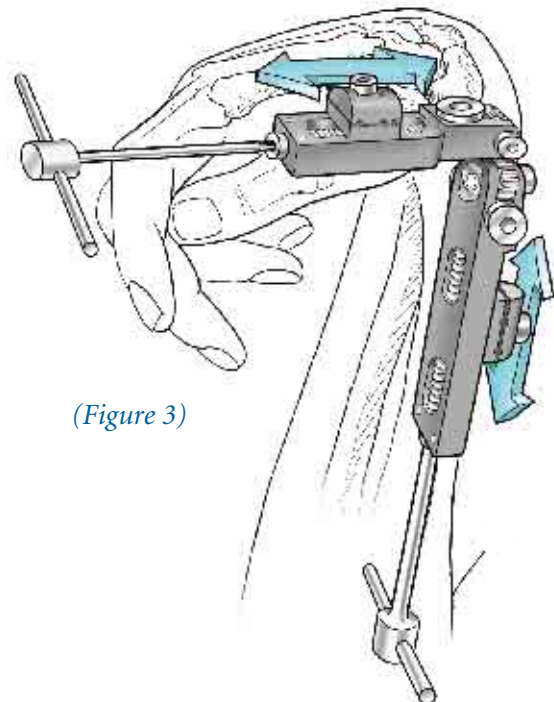
(Figure 1)



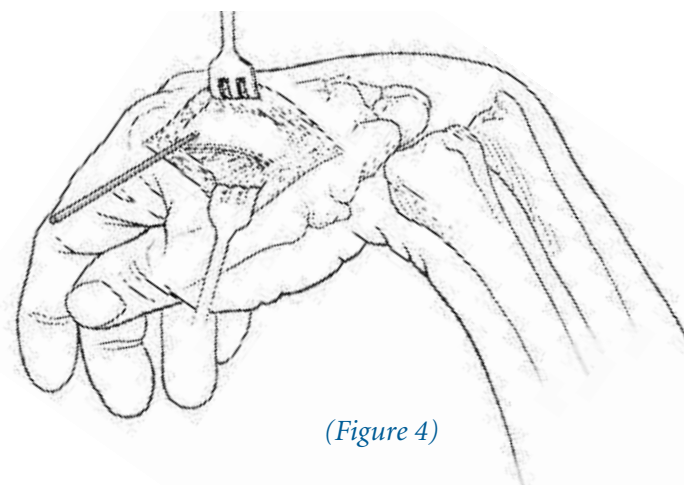
(Figure 2)

2. Manipulate the rails to match the required position of correction, using a 3 mm 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 3 mm wrench in the compression/distraction screw at the end of the rail segments. (Figure 3)



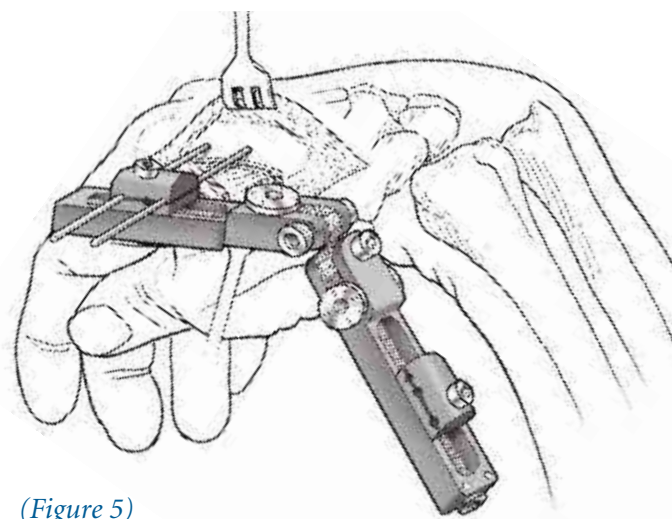
(Figure 3)



(Figure 4)

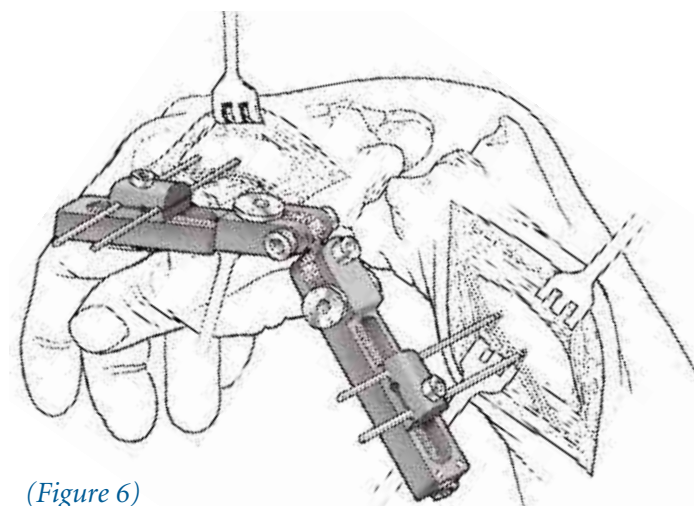
4. Make a longitudinal incision over the central axis of the 2nd metacarpal at the proposed position of the screw, on the radial side and in the frontal plane, and expose the bone subperiosteally. Insert the first 3mm screw in the frontal plane, at 90° to the long axis of the bone. (Figure 4)

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



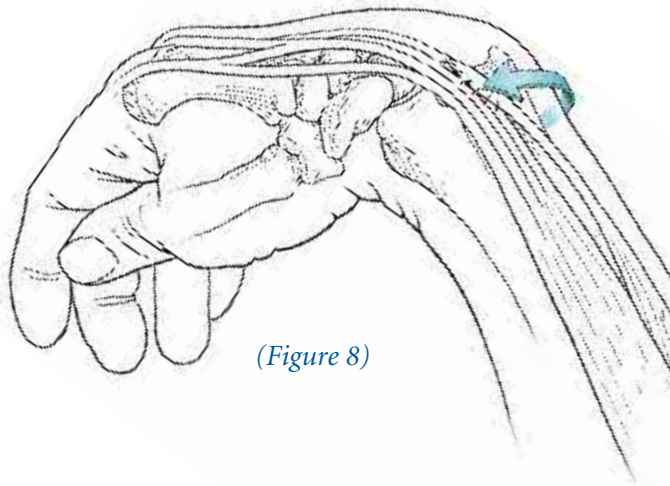
(Figure 5)

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. Only 1-2 mm of the screw tip should protrude through the second cortex to avoid the risk of damage to the soft tissues. Due to the tapered design, conical screws should not be advanced too far, as they will become loose if they are backed out. With both screws inserted, the clamp locking screw is tightened with a 3mm wrench. (Figure 5)



(Figure 6)

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 3 mm wrench. (Figure 6)
7. Confirm with an Image Intensifier that the screws are positioned accurately and that they all engage both cortices.

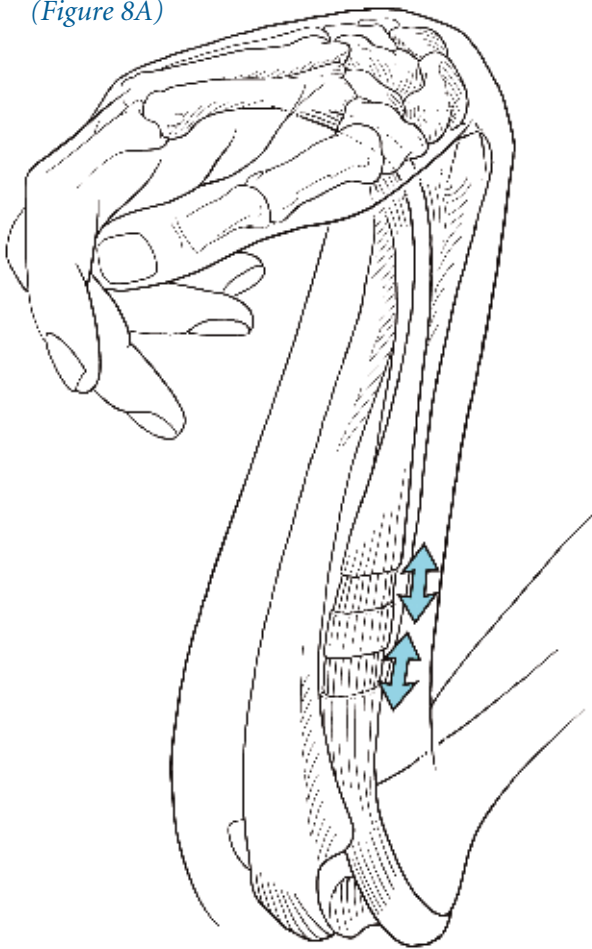


(Figure 8)

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.

(Figure 8A)

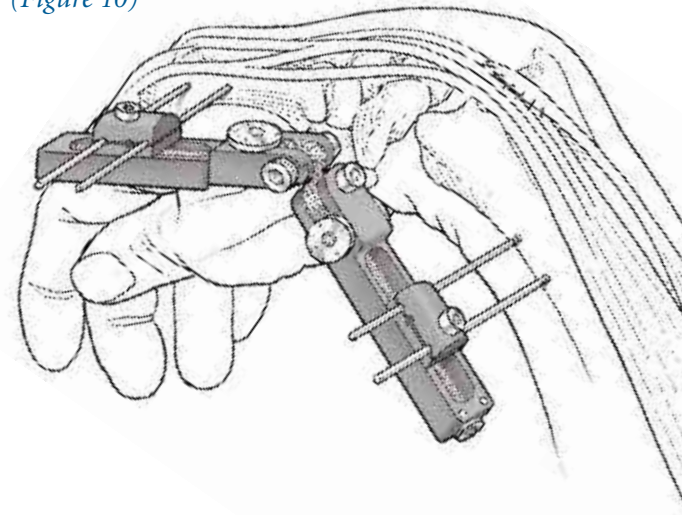


Additional staged tendon release procedures are usually required in the correction phase. The description of these procedures is beyond the scope of this manual. They should be carried out according to best practice as defined in the medical literature.

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 3 mm wrench. (Figure 10)

(Figure 10)

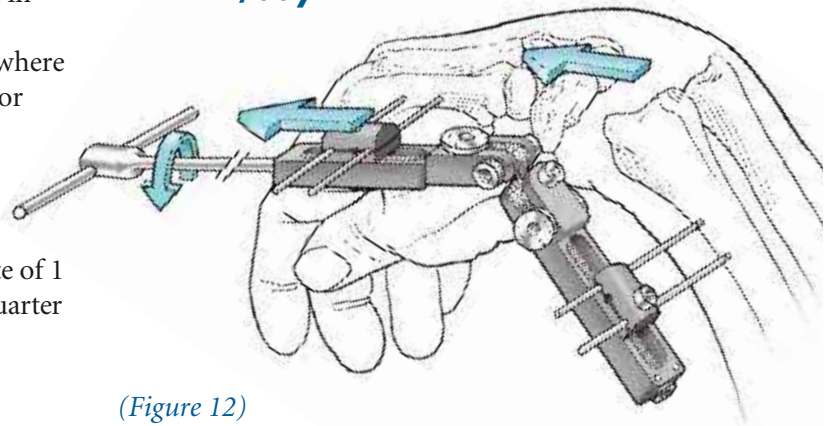


POST OPERATIVE MANAGEMENT

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.

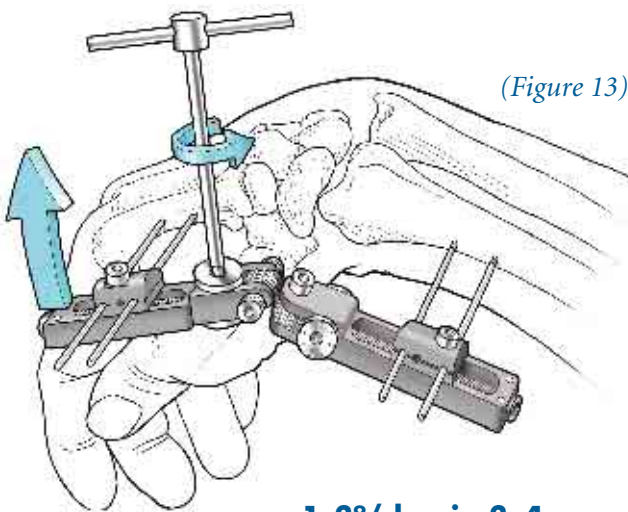
12. Longitudinal distraction may be required, at a rate of 1 mm per day, which is accomplished with a one quarter clockwise turn of the distal rail compression/distraction screw, four times a day, producing in all 4-5 mm of total distraction. Depending on the stiffness of the soft tissue it may be necessary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

**1 mm/day =
1/4 clockwise turn
4X/day**



(Figure 12)

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)



(Figure 13)

**1-3°/day in 3-4
increments daily**

Although additional staged surgeries may be required, the outcome should be improved range of dorsiflexion, grasp capabilities, release and ability to assist in daily activities.

General

- Unless supplied sterile, all Orthofix medical devices must be sterilized prior to surgical use.
- A new product means any device taken out of its original Orthofix packaging.

Recommended decontamination process

The following sequence of processes is recommended for rendering the Orthofix Fixation System devices which are supplied non-sterile safe for their **first clinical use**:

1. CLEANING
2. STERILIZATION

Preparation for cleaning of new products

- When applicable, the device should be disassembled completely.
- Wherever possible, all parts of disassembled devices should be kept together in one container.
- For disassembly/reassembly the specific instrumentation should be used as described in detail in the Operative Manuals.

STEP 1: Cleaning of new products

- REMOVE products from their original packaging. All equipment should be carefully examined prior to use to assure proper working condition.
- CLEAN with a woven-non woven tissue soaked using a solution of 70% medical grade alcohol and 30% distilled water or with compatible detergent. **Detergents with fluoride, chloride, bromide, iodide or hydroxyl ions MUST NOT be used.**
- RINSE with sterile distilled water.

STEP 2: Drying

- HAND-DRY carefully, using absorbent, non-shedding cloth or industrial hot hair dryer, or place into drying cabinet.

STEP 3: Sterilization of new products

- Prior to surgical use, new products should be cleaned as described at Step 1.
- PACKAGING: Where products are to be packaged to maintain their sterility after sterilization and to prevent damage of the instrument prior to use, an appropriate medical grade packaging material should be used. Ensure that the pack is large enough to contain the instruments without stressing the seals.
- STERILIZATION CONTAINERS: Instruments may be loaded into a dedicated instrument tray, or general-purpose sterilization tray. Ensure that cutting edges are protected and do not exceed the recommended content or maximum weight indicated by manufacturer.
- PRECAUTIONS: Fixators can be sterilized in the assembled state as long as ball-joints, central body locking nut and clamp locking screws are left untightened. If any joints are tightened, they may sustain damage from thermal expansion during the sterilization process.
- STERILIZATION: Sterilize by steam autoclaving, utilizing a pre-vacuum cycle. *Orthofix recommends the following cycle: Steam autoclave 132-135°C (270-275°F), minimum holding time 10 minutes.*
- Any other **validated** pre-vacuum autoclave cycle may be used in alternative.

Instructions for Reprocessing of Reusable Devices for Subsequent Re-Use

General

- Unless supplied sterile, all Orthofix devices must be sterilized prior to surgical use.
- PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED.
- Repeated reprocessing has minimal effect on reusable instruments. End of life is normally determined by wear and damage due to use.

Recommended decontamination process

The following sequence of decontamination processes is recommended for **reprocessing re-usable Orthofix Fixation System medical devices** and rendering them safe for subsequent clinical use.

1. CLEANING
2. DISINFECTION
3. STERILIZATION

Preparation at the point of use of used devices

- All **used** surgical instruments should be regarded as **contaminated**. Their handling, collection and transportation should be strictly controlled to minimise any possible risks to patients, personnel and any area of the healthcare facility.
- It is recommended that instruments are reprocessed as soon as is reasonably practicable following use.
- Ensure that items are securely and safely packaged during transport to the decontamination area.

Preparation for cleaning of used devices

- Used fixators should be disassembled completely, and all cams and bushes discarded since they are not re-usable.
- All components should be inspected, since damage to the surface of metal components can reduce the strength and fatigue resistance and may lead to corrosion.
- Wherever possible, all parts of disassembled devices should be kept together in one container.
- For disassembly/reassembly, the specific instrumentation should be used as described in detail in the Operative Manuals.

STEP 1: Cleaning of used products

- Cleaning is an essential pre-requisite to ensure effective disinfection or sterilization.
- The preferred method of decontamination of used devices is mechanical cleaning followed by disinfection.
- Where an automated washer-disinfector is not available, manual cleaning may be used, followed by disinfection.

Manual Cleaning (by immersion)

Equipment required:

- a sink (not hand wash basin) or receptacle which will hold enough detergent so that the item of equipment to be cleaned can be fully immersed;
- a detergent solution. **Orthofix recommends use of a 0,3% enzymatic detergent solution, immersion for 30 minutes at 40°C (104°F).** Detergents with fluoride, chloride, bromide, iodide,

or hydroxyl ions [free halogen ions or sodium hydroxide] **MUST NOT be used;**

- a receptacle to contain rinse water;
- a drainage surface;
- a clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (drying cabinet or industrial hot air dryer);
- a brush and jet washer.

Procedure:

- I. Ensure that the cleaning receptacle is clean and dry.
- II. Wearing protective equipment, fill the receptacle with sufficient water/detergent solution.
- III. Carefully immerse all components in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including those of devices that have holes or recesses or are cannulated.
- IV. Brush, wipe, agitate, irrigate, jetwash or hand spray the item to dislodge and remove all visible dirt, ensuring that the action is performed beneath the surface of the solution.
- V. Remove the items from the solution and drain.
- VI. Remove any residue with a brush in running water.
- VII. Soak in sterile distilled water to remove traces of hard water.
- VIII. Remove item from rinse water and drain.
- IX. Carefully hand-dry using absorbent, non-shedding cloth or an industrial hot air dryer, or place in a drying cabinet.
- X. Complete the necessary documentation.
- XI. Proceed with disinfection.

Mechanical Cleaning (using an automated washer)

- Mechanical cleaning followed by disinfection is the preferred method of decontamination of used devices.
- If a washer-disinfector is used, it must have a validated cycle.
- Ensure that the washer-disinfector and all services are operational.
- Select and start a cycle according to the recommendations of the washer manufacturer
- **Detergents with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used.**
- Proceed with disinfection.

STEP 2: Disinfection

Disinfection Procedure (manual)

Equipment required:

- a sink (not hand wash basin) or receptacle which will hold enough disinfectant so that the item of equipment to be cleaned can be fully immersed;
- a compatible water/disinfectant solution at dilution and temperature recommended by its producer. **Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used; Orthofix recommends use of 3% hydrogen peroxide, with immersion, for 3 hours at room temperature;**
- a receptacle to contain rinse water;
- a drainage surface;
- a clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (drying cabinet or industrial hot air dryer);
- a brush and jet washer.

Procedure:

- I. Wearing protective equipment, fill the receptacle with sufficient disinfectant solution to ensure complete immersion of the item.
- II. Carefully immerse all components in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including those of cannulated devices.
- III. Leave the items for the time required (3 hours with 3% Hydrogen Peroxide).
- IV. Remove the items from the solution and drain.
- V. Remove any residue with a brush in running water.
- VI. Soak in sterile distilled water to remove traces of hard water.
- VII. Remove item from rinse water and drain.
- VIII. Carefully hand-dry using absorbent, non-shedding cloth or industrial hot hair dryer, or place in a drying cabinet.
- IX. Complete the necessary documentation.
- X. Proceed with sterilization.

Disinfection Procedure (automatic)

Equipment required:

- I. A thermal washer-disinfector, cabinet or continuous process type.
- II. A sufficient number of racks for stacking items to be processed.
- III. A compatible disinfectant and rinse aid. **Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] must not be used; Orthofix recommends use of 0,5% phenolic disinfectant solution at 80°C (176°F). The validated cycle time is 80 minutes.**
- IV. A drainage surface.
- V. A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.

Procedure:

- I. Ensure the washer-disinfector and all services are operational.
- II. Wear protective equipment, load the rack/machine ensuring that the loading configuration does not impede the cleansing process.
- III. Select and start a cycle according to the recommendation of the washer manufacturer. On completion on the cycle, ensure that all stages and parameters have been achieved; remove the load and visually check and inspect the cleanliness of the item, drain off excessive water and dry if necessary.
- IV. Complete the documentation.
- V. Proceed with sterilization.

Disinfection Procedure (ultrasound)

Equipment required:

- I. An ultrasonic washer with lid which will hold enough liquid so that the items of equipment to be cleaned can be fully immersed.
- II. A sufficient number of supporting racks or trays for stacking items to be processed.
- III. A timing device.

- IV. A compatible water-detergent solution at dilution and temperature, recommended by manufacturer.
- V. A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.

Procedure:

- I. Ensure the ultrasonic washer is clean and dry prior to use.
- II. Wear protective equipment, fill the fluid reservoir with sufficient water/disinfectant to ensure complete immersion of items. **Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] must not be used; Orthofix recommends use of 0,5% phenolic disinfectant solution immersion at 50°C (122°F) for 15 minutes (ultrasound frequency 50/60 Hz).**
- III. Switch on and leave for required time to degas the water.
- IV. Remove lid and carefully immerse the item in the fluid ensuring that any air contained within the item is displaced. Irrigate cannulated devices.
- V. Re-place the lid and leave for the time recommended (15 minutes).
- VI. Switch off, lift the lid, remove the item and drain before transferring to a clean-rinse receptacle.
- VII. Rinse thoroughly with clean water, ensuring irrigation of lumen devices, and drain.
- VIII. Carefully hand-dry using absorbent, non-shedding cloth, industrial hot air dryer or place in a drying cabinet.
- IX. Complete the documentation.
- X. Proceed with sterilization.

STEP 3: Drying

Carefully hand-dry using absorbent, non-shedding cloth or industrial hot air dryer, or place in a drying cabinet.

STEP 4: Inspection, maintenance and testing

- All instruments and product components should be visually inspected for cleanness and any signs of deterioration that may cause failure in use (such as cracks or damage to surfaces) and functions tested before being sterilized (see detailed Operative Technique Manuals and Instructions for use). Particular attention should be given to:
 - Cannulated devices (NB: cannulated drill-bits are single-patient use only)
 - Cutting edges: Discard blunt or damaged instruments
 - Hinged instruments: check for smooth movement of hinges without excessive "play".
 - Locking mechanisms should be checked for action.
- If a component or instrument is believed to be faulty, damaged or suspect, it should NOT BE USED.
- When instruments form part of an assembly, check assembly with matching components.
- Lubricate all parts, except for cam, bush and ball coupling with Orthofix silicone oil whenever required (see detailed Operative Technique Manuals).
- Final locking of the ball-joints of the 10000, 30000/31000 or 90000 range of fixators is performed with a torque wrench, which must be turned in a clockwise direction only. A click indicates that the correct torque has been applied. Any attempt to unlock the cam or any screw using the torque wrench will dam-

age its gearing. The torque wrench is pre-set at a specific value, which is 15 Nm±0.5 for the 30000/31000 Range (30025) and 27 Nm±1 for the 10000 and 90000 Ranges (10025). This value should be checked at least every two years or any time the instrument becomes damaged, by returning it to the local authorized representative. The cams and bushes in the ball joints of the 10000, 30000, 31000 and 90000 range of fixators must be replaced after every use.

Note: If on tightening the cams and bushes with the torque wrench, the mark on the cam moves more than 170° from the fully unlocked position, all cams and bushes must be replaced. If the problem persists, the whole fixator should be replaced. The use of a torque wrench is not required for final locking of the ball joints in the XCaliber External Fixator. Final locking is achieved with the Allen Wrench. The cams can be locked from either side of the clamp. They should be turned towards the thicker section of the coloured insert until tightly closed, and the cam is at least 50% of the way across the recess.

STEP 5: Sterilization

- **PACKAGING:** Where products are to be packaged to maintain their sterility after sterilization and to prevent damage of the instrument prior to use, an appropriate medical grade packaging material should be used. The pack should be large enough to contain the instruments without stressing the seals.
- **STERILIZATION CONTAINERS:** Instruments may be loaded into a dedicated (Orthofix) instrument tray, or general-purpose sterilization tray. Cutting edges should be protected and the recommended content or maximum weight not exceeded as indicated by manufacturer.
- **PRECAUTIONS:** Fixators can be sterilized in the assembled state as long as ball-joints, central body locking nut and clamp locking screws are left untightened. If any joints are tightened, they may sustain damage from thermal expansion during the sterilization process.
- **STERILIZATION:** Sterilize by steam autoclaving, utilizing a pre-vacuum cycle. *Orthofix recommends the following cycle: Steam autoclave 132-135°C (270-275°F), minimum holding time 10 minutes.*
- Any other **validated** pre-vacuum autoclave cycle may be used in alternative.
- Processed items should be stored in clean and secure stores to avoid damage or tampering.

Disclaimer: "The instructions provided above have been validated by Orthofix as being a true description of the preparation of a device for first clinical use or for re-use of multiple use devices. It remains the responsibility of the reprocessor to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. The cleaning, disinfection and sterilization processes should be adequately recorded. Likewise any deviation by the reprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences and should also be appropriately recorded"

M190	Sterilization Tray, Empty: can be ordered separately and used for sterilizing the MultiPlanar MiniRail
M210	T-Wrench for Bone Screws
M211	Quick Connect Unit for the Drill
13570	T-Wrench for Clamp Screws
10012	Allen Wrench 3 mm
M300	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 2.5-2 mm total length 40 mm, and thread length 15 mm
M301	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 2.5-2 mm total length 45 mm, thread length 20 mm
M310	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0 - 2.5 mm total length 50 mm, thread length 18 mm
M311	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0 - 2.5 mm total length 60 mm, thread length 20 mm
M312	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0 - 2.5 mm total length 60 mm, thread length 25 mm
M313	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0 - 2.5 mm total length 60 mm, thread length 30 mm
M314	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0 - 2.5 mm total length 70 mm, thread length 20 mm
M315	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0 - 2.5 mm total length 70 mm, thread length 25 mm
M316	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0 - 2.5 mm total length 70 mm, thread length 30 mm
M317	Self-Drilling Cortical Screws shaft \varnothing 3 mm, thread \varnothing 3.0-2.5 mm total length 100 mm, thread length 30 mm
M420	Threaded Wires 1.6 mm (pack of 4), total length 70 mm, thread length 15 mm
M426	Threaded Wires 2.0 mm (pack of 4), total length 100 mm, thread length 15 mm
M511	M2 MultiPlanar MiniRail Fixator

Quick Reference Screw Ordering Guide

3.0 - 2.5 mm Thread Diameter / Shaft Diameter 3 mm

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

Quick Reference Screw Ordering Guide

2.5 - 2.0 mm Thread Diameter / Shaft Diameter 3 mm

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

Your Distributor is:

www.orthofix.com

