ORDERING INFORMATION

**Sterilization box, empty M190**
Can accommodate:

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M101</td>
<td>Standard MiniRail lengthener</td>
</tr>
<tr>
<td>M102</td>
<td>Long MiniRail lengthener</td>
</tr>
<tr>
<td>M103</td>
<td>Short MiniRail lengthener</td>
</tr>
<tr>
<td>M104</td>
<td>MiniRail lengthener T-clamp</td>
</tr>
<tr>
<td>M111</td>
<td>Articulated MiniRail fixator-horizontal axis</td>
</tr>
<tr>
<td>M122</td>
<td>Articulated MiniRail fixator-vertical axis</td>
</tr>
<tr>
<td>M210</td>
<td>T-wrench for bone screws</td>
</tr>
<tr>
<td>M300</td>
<td>Self-drilling cortical screws shaft Ø 3mm, thread Ø 2.5-2mm, total length 40mm, thread length 15mm</td>
</tr>
<tr>
<td>M301</td>
<td>Self-drilling cortical screws shaft Ø 3mm, thread Ø 2.5-2mm, total length 45mm, thread length 20mm</td>
</tr>
<tr>
<td>M420</td>
<td>Threaded wires Ø 1.6mm (pack of 4), total length 70mm, thread length 15mm</td>
</tr>
<tr>
<td>M426</td>
<td>Threaded wires Ø 2.0mm (pack of 4), total length 100mm, thread length 15mm</td>
</tr>
<tr>
<td>M442</td>
<td>Threaded wire extractor</td>
</tr>
<tr>
<td>10012</td>
<td>Allen wrench 3mm</td>
</tr>
<tr>
<td>13570</td>
<td>T-wrench for clamp screws</td>
</tr>
</tbody>
</table>
GENERAL POINTS

Bone fixation

The system is provided with 2 types of bone fixation:

1. Self-drilling screws, 3mm shank, with a tapered thread 2.5 - 2.0mm.
2. Threaded wires, 2mm shank, with a cylindrical thread 15mm long. Sizes supplied are 70/15, with a thread diameter of 1.6mm, and 100/15, with a thread diameter of 2.0mm.

In addition, larger self-drilling screws are available, with a 3mm shank, but with a tapered thread diameter 3.0-2.5mm.

- In the foot, the largest diameter implant should be selected compatible with the bone diameter, remembering that the diameter of the hole in the bone should never be larger than 30% of the bone diameter at that point. 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.

- All the screws have tapered threads. Care should be taken that they are not inserted too far, because they should not be backed out, as this will cause loosening.
  NB: If this happens with the 2.5-2.0mm threads, a screw with a larger thread can be inserted instead.

- The wires have cylindrical threads, and can therefore be backed out if necessary.

- In the diaphysis, screw or wire insertion should always be in the centre of the bone axis, to avoid causing weakening.

Fixator application

- The clamps should face down, beneath the fixator body, in cases where one is concerned with the body of the fixator striking the ground during weightbearing (metatarsal 1 and 5, calcaneus) or rubbing against adjacent soft tissues (metatarsals 2-4).
USE OF M 103 IN LENGTHENING OF A CONGENITALLY SHORT 4th METATARSAL

Insert a 2mm diameter threaded wire (or 3mm diameter bone screw) at 45° from the frontal plane and at right angles to the bone axis. Apply the MiniRail lengthener over the wire (or screw). Insert a second wire (or screw) into a screw seat in the second clamp.

Insert the remaining threaded wires (or screws). Perform an osteotomy mid-way between the two clamps.

If a metaphyseal osteotomy is required, use the T-Clamp to place two screws or wires across the axis of the bone.

Insert a K-wire longitudinally through the metatarsophalangeal joint to prevent any subluxation during callus distraction.
**Post-operative management**

Wait for 7-10 days before commencing distraction. Distract at a rate of 1mm per day (one quarter turn clockwise of the threaded screw four times a day). Callus formation should be carefully monitored with standard radiographs weekly.

**Special considerations in other metatarsal applications**

1st or 5th metatarsal

Apply the fixator in the frontal plane.

2nd or 3rd metatarsal

Incline wires (or screws) dorsally at an angle of 45° to the frontal plane.

**USE OF M 111 IN TREATMENT OF JOINT STIFFNESS (HALLUX RIGIDUS)**

Insert a 2mm Kirschner wire into the head of the first metatarsal from the medial side, so that it is in the centre of rotation of the joint. Orientate the fixator so that the body of the fixator with the distraction mechanism is facing the proximal phalanx. The hexagon at the hinge should face outwards (it may be necessary to transpose the two components of the hinge to achieve this). Slide the articulating hinge over the Kirschner Wire. Insert a 2mm threaded wire (or 3mm diameter bone screw) in the distal seat of the distal clamp and a second wire or screw into the proximal seat of the distal clamp. Check that the movement of the joint is about the axis of the Kirschner wire; if not, remove it and re-site it, adjusting the distraction mechanism as necessary.
USE OF M122 IN PAEDIATRIC METATARSUS ADDUCTUS

5 year old girl with right metatarsus adductus. AP X-ray shows medial deviation of metatarsals 2-5 at the Lisfranc's joint.

Distract 5mm acutely (intraoperatively). Remove the K-wire and tighten the articulated body locking screw.

Post-operative management

Wait 3 days following surgery and begin gradual distraction. Distract the joint 0.5mm/day until a joint space two or three times the normal width is obtained (one full turn clockwise of the threaded screw = 1mm distraction). When the soft tissues have relaxed, loosen the articulated body locking screw to commence physiotherapy. At the end of an exercise period, place the hallux in the neutral position and retighten the articulated body locking screw. Two weeks following completion of distraction, remove the fixator.

Insert wires or screws into the distal end of the first metatarsal.
Soft tissue

Perform the following:
- Percutaneous tendo achilles lengthening
- Abductor hallucis release
- Partial anterio tibial tendon resection
- Capsulotomies 2-5

Orientate the MiniRail fixator on the medial side of the first metatarsal with the shorter hinged side distal on the foot.

Two distal screws or wires are inserted from the medial side into the first metatarsal, distal to the growth plate, in the coronal plane at 90 degrees to the axis of the bone.

The fixator hinge is orientated to accommodate the angle between the forefoot and hindfoot, so that screws inserted into the calcaneus are at 90 degrees to the bone axis.
Orientate hinge on fixator to accommodate the appropriate alignment of the forefoot with the rearfoot.

Two proximal pins are inserted into the calcaneus.
Translation of the pins in the distal clamp will provide lateral deviation of all metatarsals as required.

Post-operative management

Non-weightbearing for the first three days. Ambulation after third day as tolerated with a surgical shoe. External fixation for six weeks with casting for ten days after fixator removal. Pin site care twice a day.
See “Orthofix External Fixation System” instruction leaflet (PQ EXF) prior to use.

The Orthofix Quality System has been certified to be in compliance with the requirements of:
• Medical Devices Directive 93/42/EEC, Annex II - (Full Quality System) as amended in 2007/47/EC
• International Standards ISO 13485 / ISO 9001 for external fixator devices, implants for osteosynthesis and related instruments.

Manufactured by:
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo (Verona), Italy
Telephone +39 045 6719000, Fax +39 045 6719380

Distributed by:

Instructions for Use: See actual package insert for Instructions for Use.

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. 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.