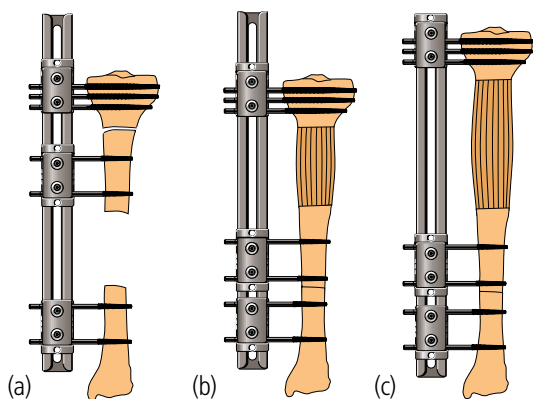


LIMB RECONSTRUCTION SYSTEM

PART A: GENERAL PRINCIPLES

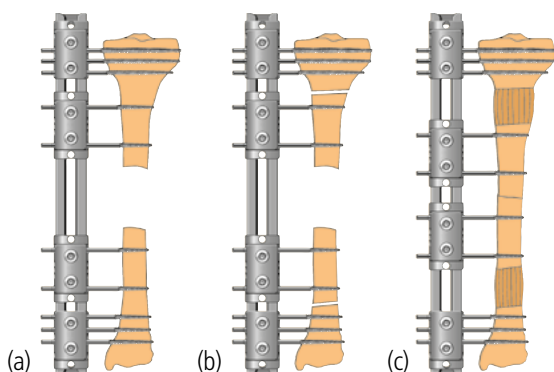
PART B: CORRECTION OF DEFORMITIES



Please kindly refer to the product IFU PQREC, 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.

INTERMEDIATE SIZE BONE DEFECT: BONE TRANSPORT

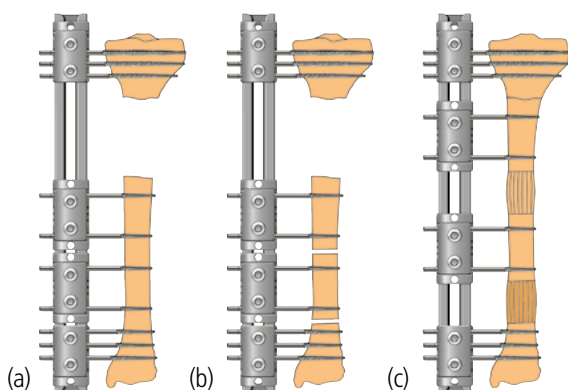
- Intermediate size distal defect with shortening. Limb Reconstruction System with 3 clamps applied.
- Proximal metaphyseal osteotomy between clamp 1 and 2, followed by transport with clamp 1 and 3 locked to the rail and clamp 2 moved distally.
- Lengthening to restore the original limb length. Clamp 2 and 3 locked to rail and clamp 1 moved proximally.



LARGE BONE DEFECT: BIFOCAL TRANSPORT

Central Defect

- Large central bony defect and Limb Reconstruction System in place.
- Proximal and distal metaphyseal osteotomies performed.
- Simultaneous proximal and distal transport with clamps 1 and 4 locked to rail and clamp 2 moved distally and clamp 3 proximally until segments meet.

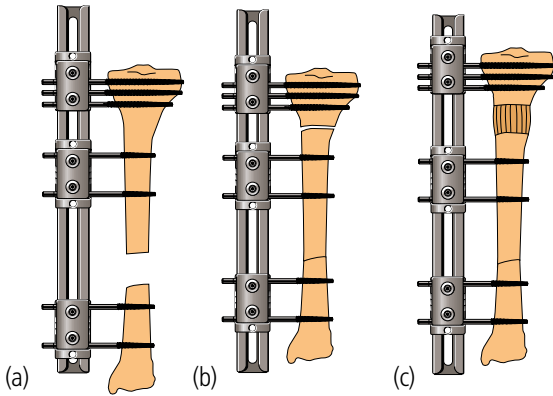


Peripheral Defect

- Large peripheral bony defect and Limb Reconstruction System in place.
- Two osteotomies performed in longer bone fragment.
- Simultaneous proximal transport with clamps 1 and 4 locked to rail and clamps 2 and 3 moved proximally until segments meet.

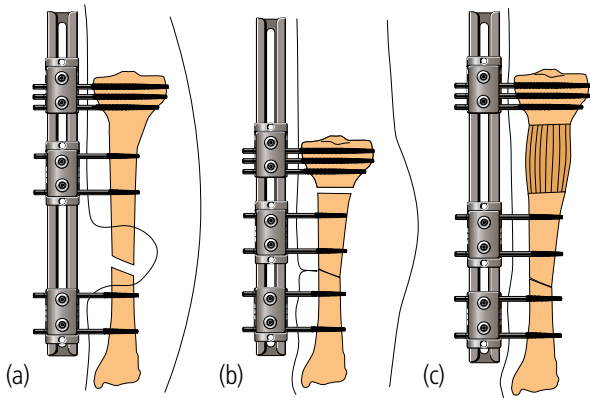
SMALL BONE DEFECT: COMPRESSION-DISTRACTION

- Small distal bone defect and Limb Reconstruction System in place.
- Immediate compression between clamps 2 and 3 to close defect. Proximal osteotomy performed between clamps 1 and 2.
- With clamps 2 and 3 locked to rail to maintain compression, clamp 1 is moved proximally to restore original limb length by Callotasis.



FRACTURES ASSOCIATED WITH MAJOR SOFT TISSUE DEFECTS: COMPRESSION- DISTRACTION

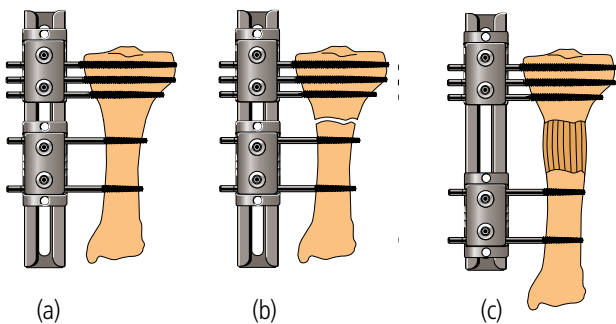
- Fracture with major soft tissue defect and exposed bone. Limb Reconstruction System in place.
- Debridement and resection of sufficient bone to allow soft tissue closure; distal stabilization; proximal osteotomy.
- Proximal distraction (lengthening) to restore original bone length.

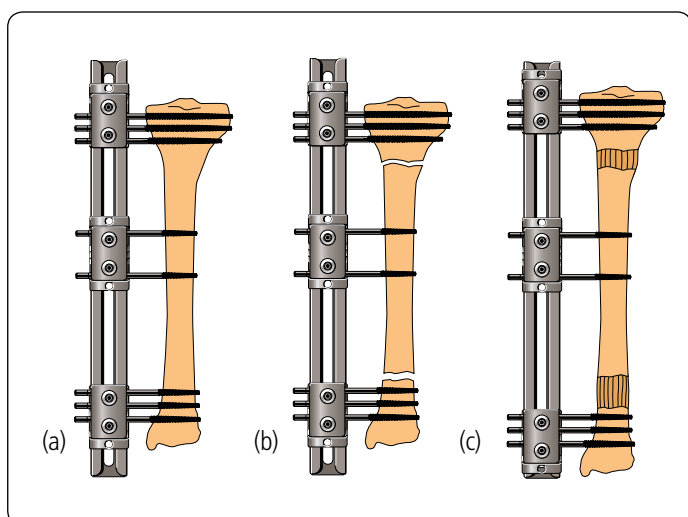


LENGTHENING

Monofocal Lengthening

- Shortening and Limb Reconstruction System in place.
- Proximal metaphyseal osteotomy.
- Distraction (lengthening) with clamp 1 locked to rail and clamp 2 free to move.





Bifocal Lengthening

- Extreme shortening in the limb, with the Limb Reconstruction System in place.
- Proximal metaphyseal osteotomy between clamps 1 and 2 and distal metaphyseal osteotomy between clamps 2 and 3.
- Simultaneous lengthening at each osteotomy site, with clamp 2 locked to the rail and clamps 1 and 3 free to move, restoring original limb length.

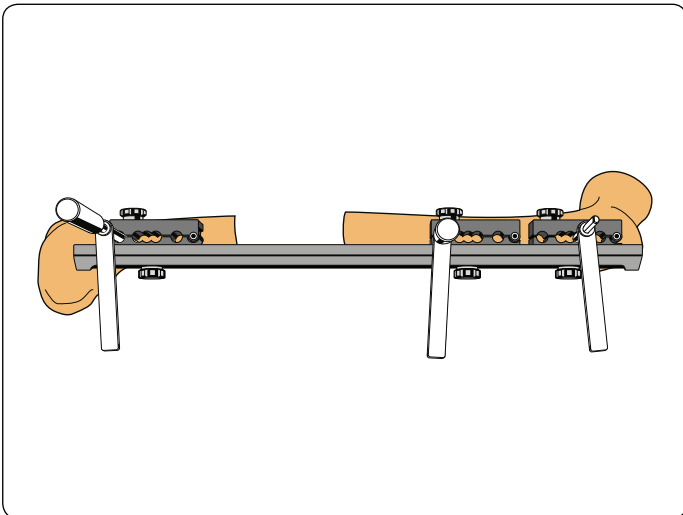
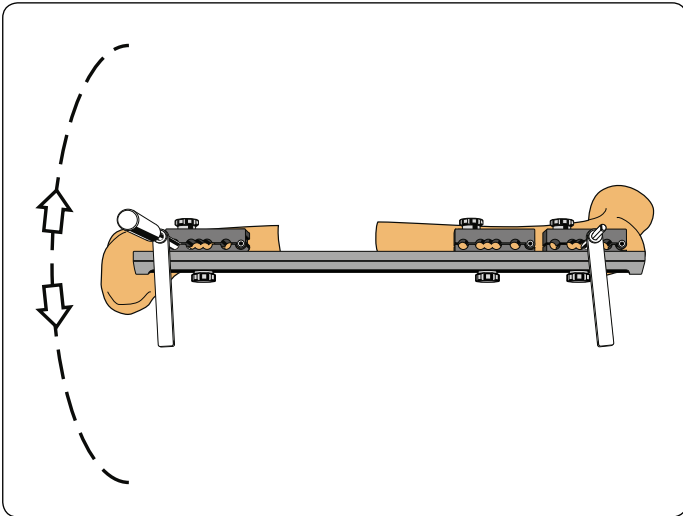
GENERAL TECHNIQUE

Screw Insertion

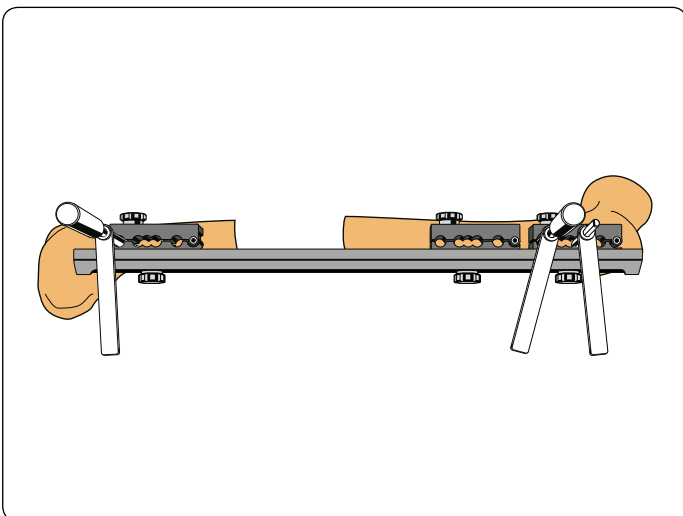
Assemble clamp templates on rail. Insert first screw in usual manner. Second screw to be inserted will be most distal one.

Identify center of bone at most distal seat of distal clamp, using trocar inserted in screw guide.

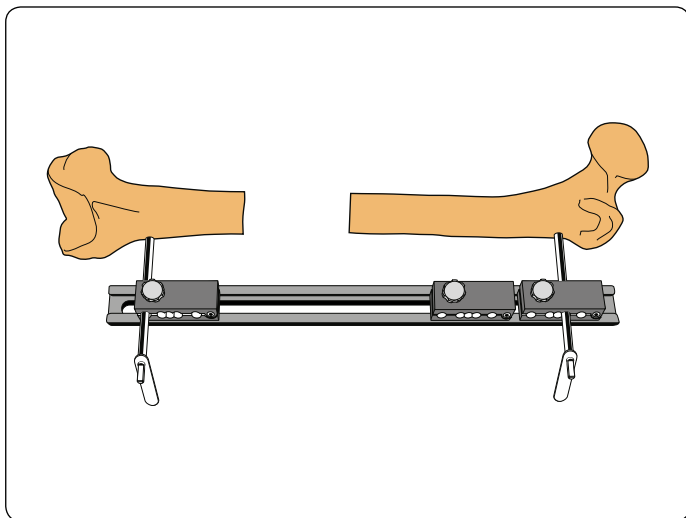
HA-Coated Osteotite™ (Osteotite hereinafter) Bone Screws are strongly recommended for all limb reconstruction procedures.



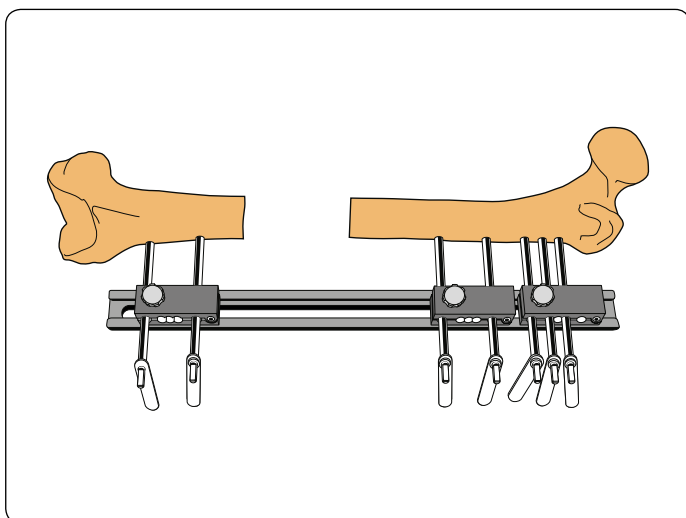
Use second trocar and screw guide to check that screws sited in outer seats of middle clamp will penetrate center of bone.



Check that satisfactory screw insertions can be achieved at chosen sites in proximal and distal clamps.



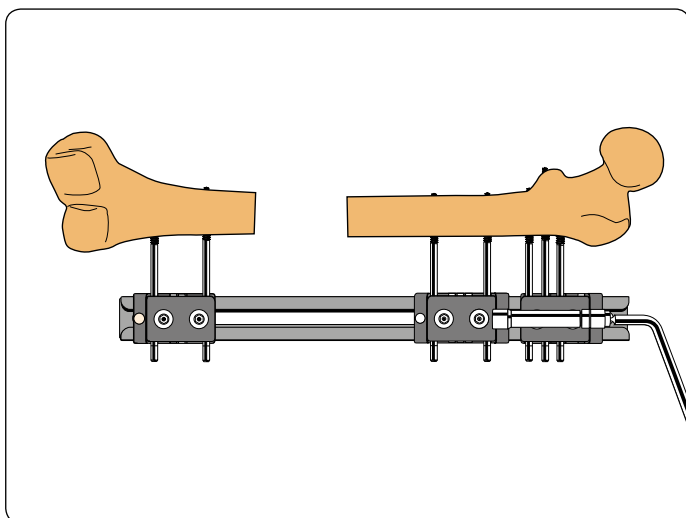
Insert most distal screw using standard technique.



Insert remaining screws.

Use screw seats 1, 2 and 4 (starting from proposed osteotomy site) in proximal clamp.

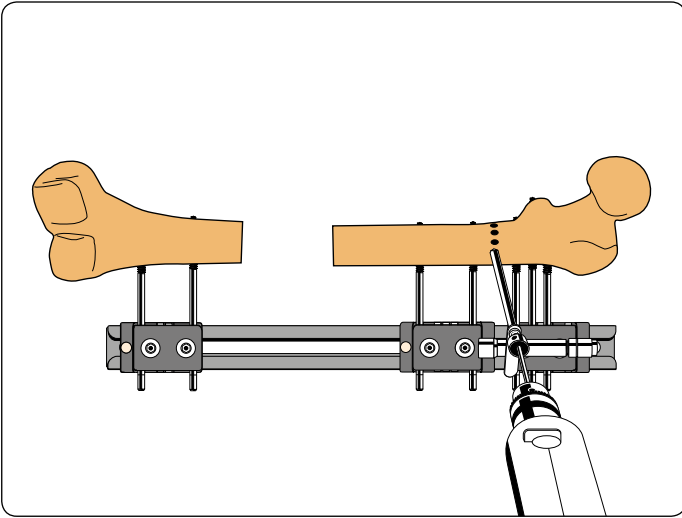
Use screw seats 1 and 5 in middle and distal clamp.



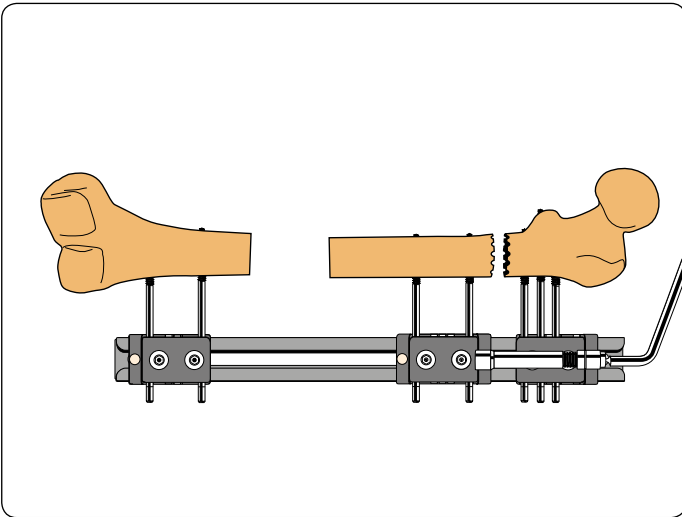
Tension Osteotomy

Remove rail with template clamps and screw guides; apply rail with definitive clamps.

Lock clamps into position on rail. Place compression-distraction unit between proximal and middle clamps. With middle clamp loosened, apply distraction.

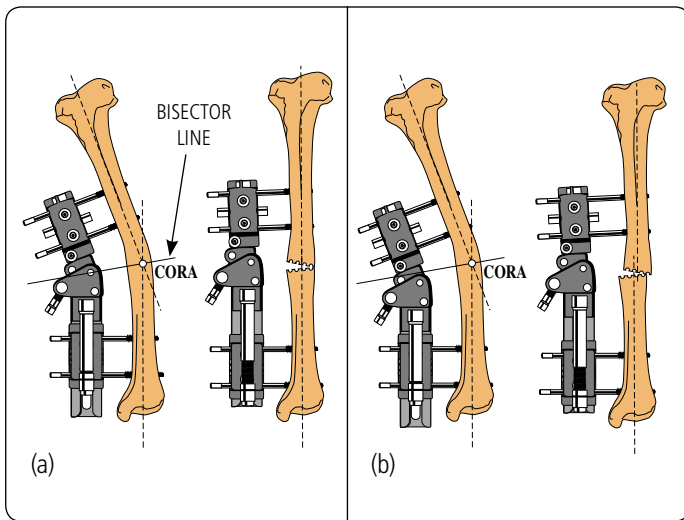


Perform osteotomy using drill bit in corresponding drill guide. Connect holes with osteotome.



Distract osteotomy to confirm complete.

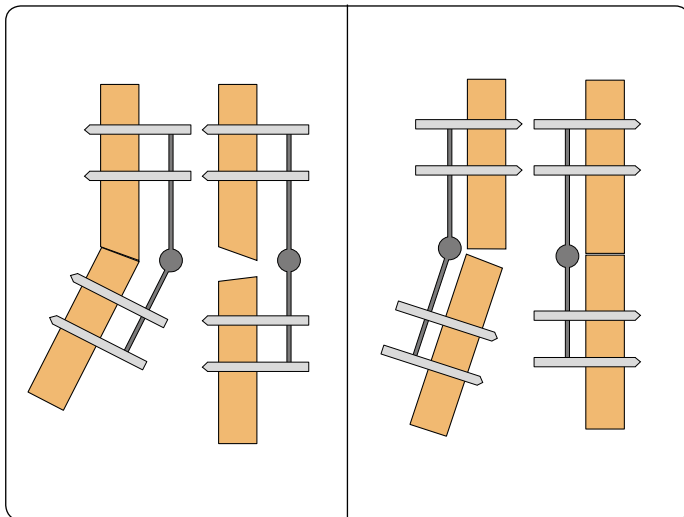
Bring both segments together and lock middle clamp. Replace periosteum, suture if possible, and close incision with single suction drain.



BASIC CONSIDERATIONS

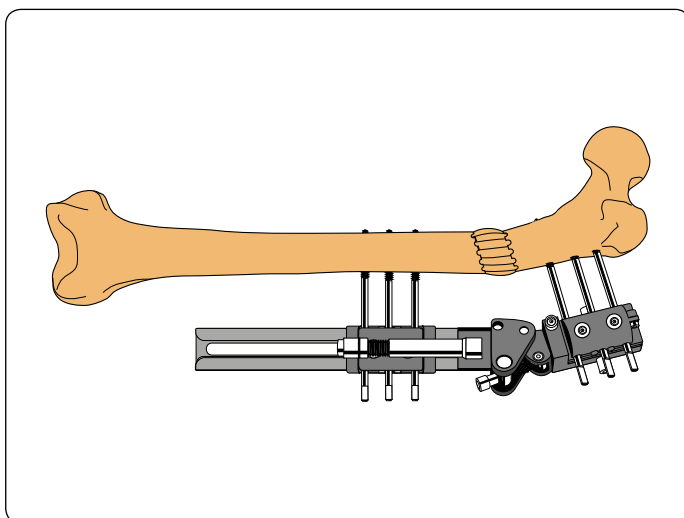
When hinge of monolateral fixator is on bisector line, after correction there is no translation (a).

When hinge is at level of deformity, after correction there is some residual translation (b).



When monolateral fixator is on convex side of deformity, correction will distract osteotomy.

When on concave side, compression will occur at osteotomy.

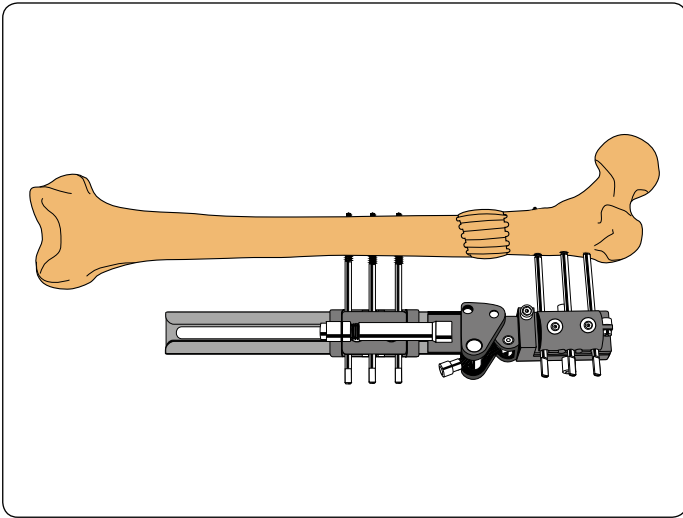


PROTOCOL FOR USE OF MICROMETRIC CORRECTION CLAMPS

Fixator on Convex Side of Deformity

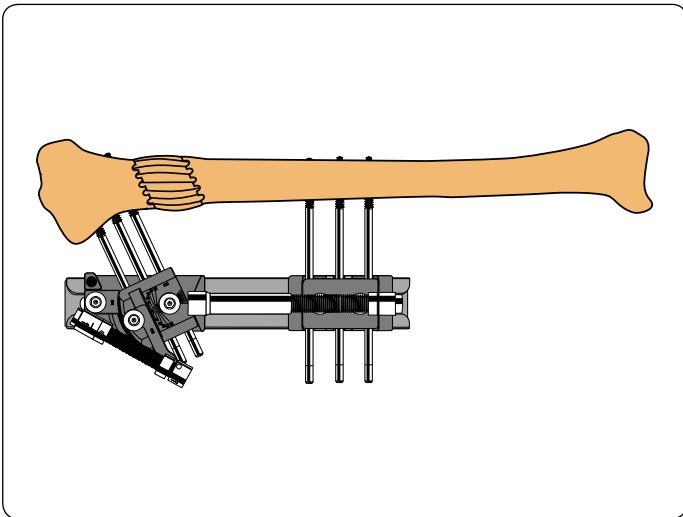
- Distract osteotomy according to principles of Callotaxis.
- Reduce soft tissue tension by shortening acutely by 4-5mm.

- c) Correction is performed until tension is felt.
- d) Repeat (b) and (c) until correction complete.

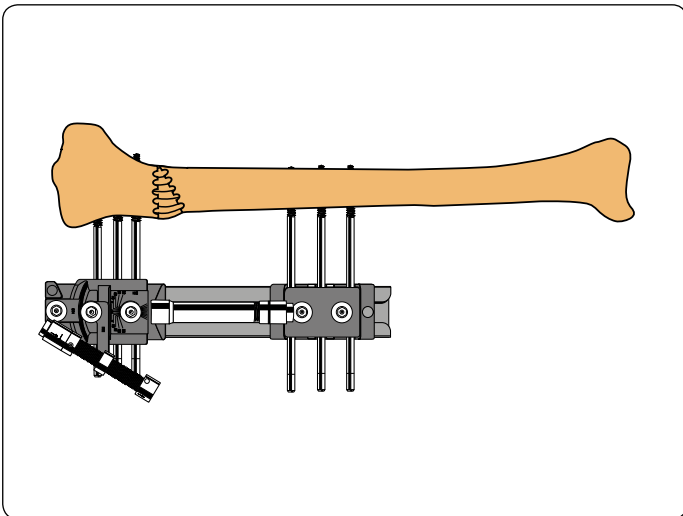


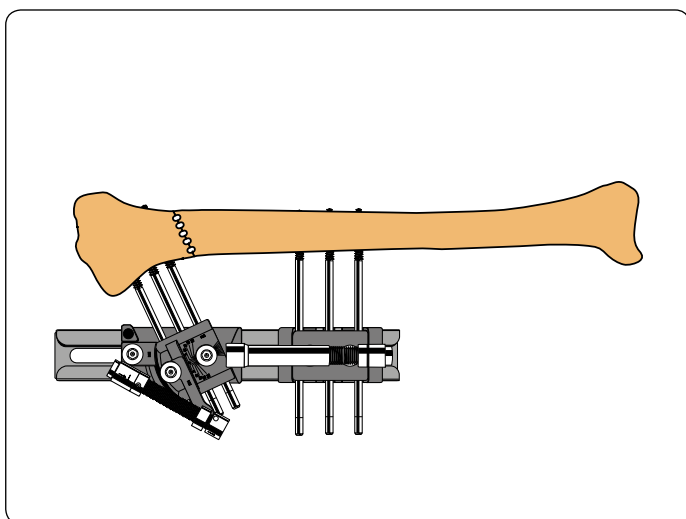
Fixator on Concave Side of Deformity

Distract osteotomy according to principles of Callotaxis.



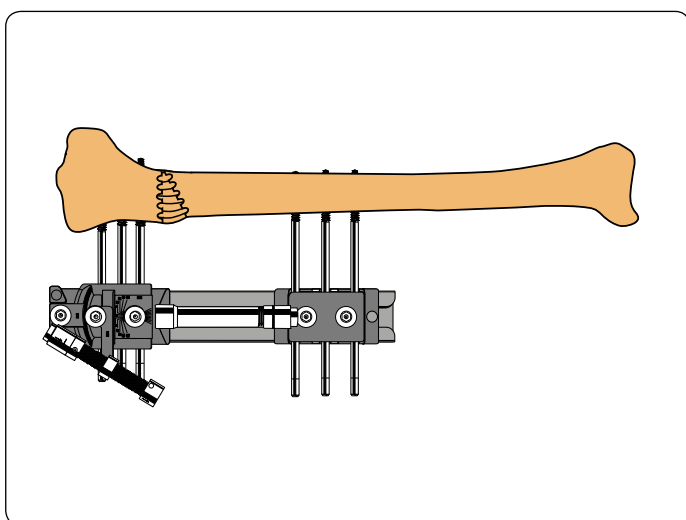
Correction is performed. As fixator is on concave side, angular correction will close distraction gap and simultaneously reduce soft tissue tension.





MICROMETRIC SWIVELLING CLAMP

Apply LRS with swivelling clamp, using template and screw guides. Osteotomy: at least 15mm from nearest bone screw, as near as possible to level of hinge.

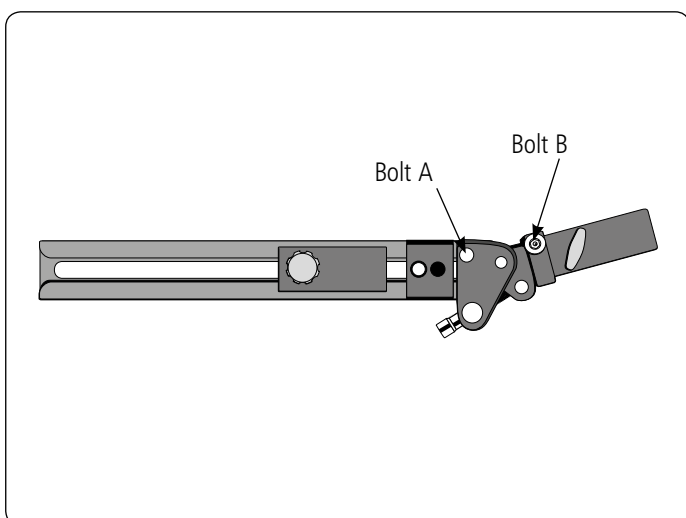


Immediate On-Table Correction

Loosen micrometric swivelling clamp on rail; loosen outer two clamp locking screws; perform correction, allowing clamp to slide on rail.

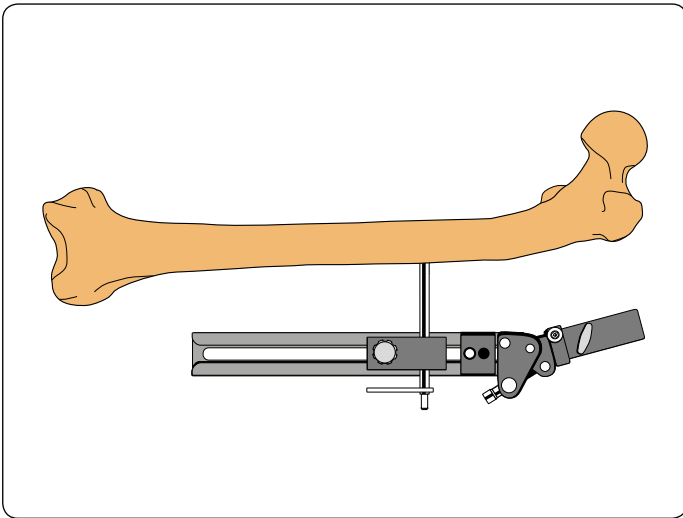
Late Correction through Callus Manipulation

See "Protocol for use of Micrometric Correction Clamps", above.



MULTIPLANAR CLAMP

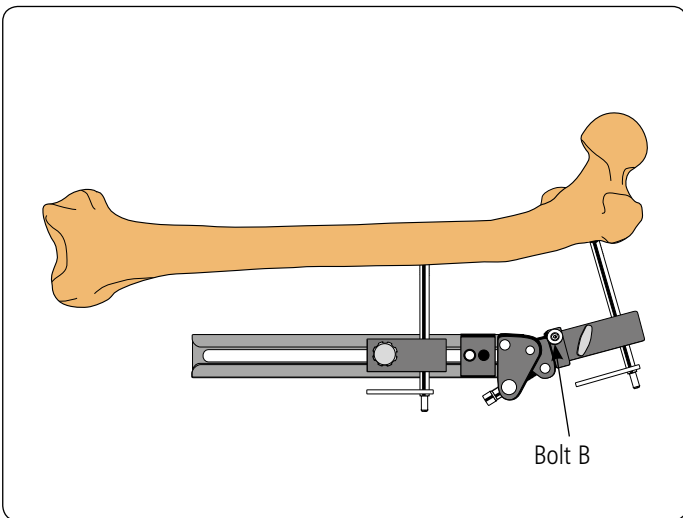
Apply LRS with swivelling clamp, using template and screw guides. Osteotomy: at least 15mm from nearest bone screw, as near as possible to level of hinge.



Mark position of CORA and bone screws on patient's limb.

Hold assembly at correct distance from skin and adjust position so that hinge is at same level as either apex of deformed bone or bisector line of CORA.

Insert bone screw through straight clamp template into longer bone segment at 90° to axis.

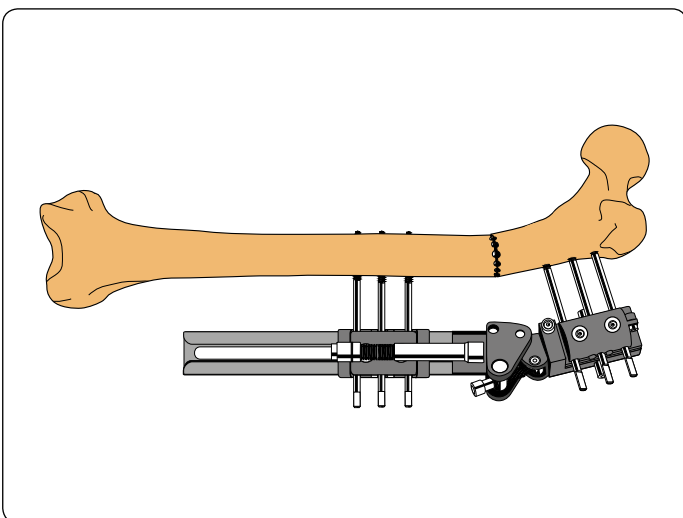


Adjust distance between rail and skin to 2-3 cm.

WARNING: The fixator should be applied at a sufficient distance from the skin to allow for post-operative swelling and for cleaning, remembering that the stability of the system depends upon the bone-fixator distance. If the fixator is sited at a distance of more than 4 cm from the bone, the use of 3 screws per clamp is advisable.

Insert screw guide and trocar through multiplanar clamp template. Check is at 90° to axis, in correct plane. If not, adjust position. Tighten bolt B.

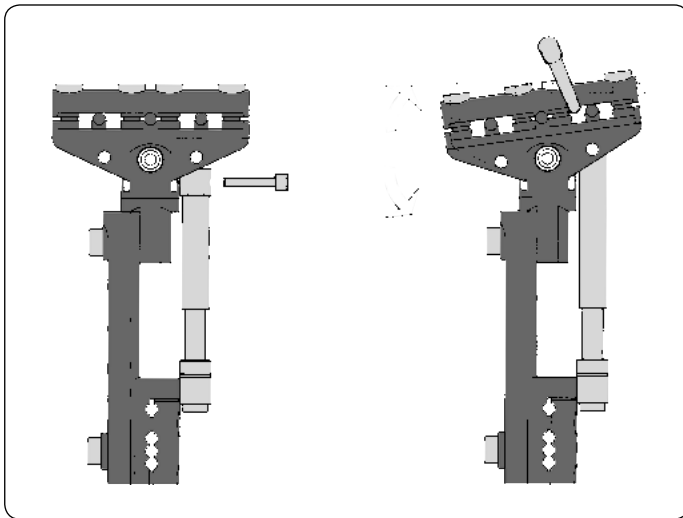
Insert second screw through multiplanar clamp template.



Insert all screws. In an adult, always use three screws per clamp.

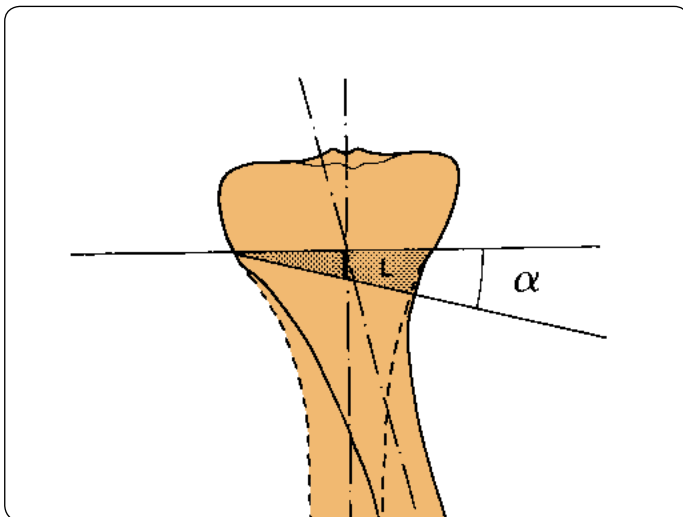
Remove screw guides and templates, apply rail with definitive clamps. Tighten firmly all clamp locking screws, perform osteotomy through apex of deformity.

For correction, follow "Protocol for use of Micrometric Correction Clamps" described above.



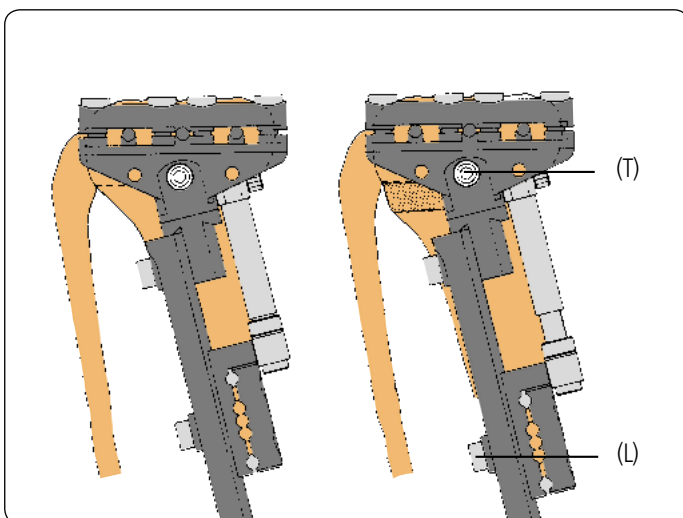
THE OF-GARCHES T-CLAMP

The OF-Garches T-Clamp may be used for lengthening, angular correction or a combination of the two. Gradual or immediate angular correction is possible.



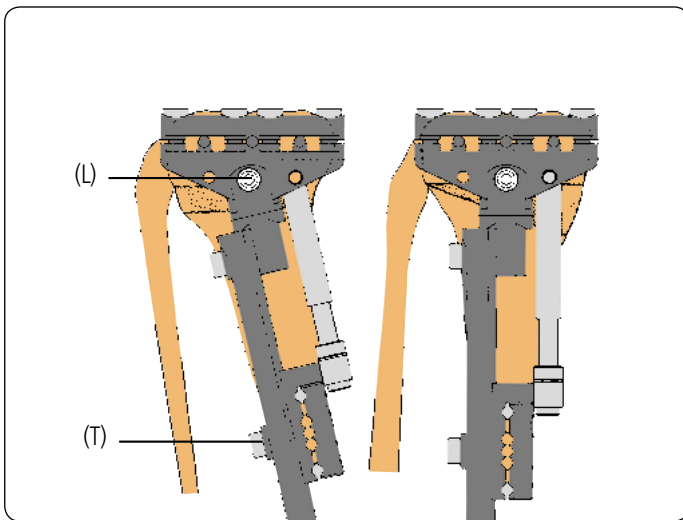
Gradual Correction

Determine pre-operatively distance L shown opposite by drawing mechanical axis of both deformed and corrected tibia.

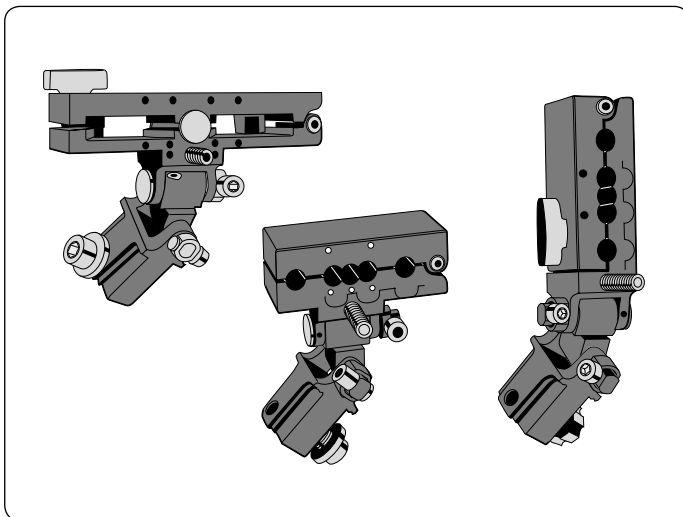


Perform complete tibial osteotomy just below insertion of patellar tendon, and a fibular osteotomy. Place compression-distraction unit in concavity of deformity and distract osteotomy according to principles of Callotasis to amount equal to distance L above.

While distracting, clamp axis locking nut (T) should be tightened and straight clamp locking screw (L) loosened.



Change position of removable locking pin, and with clamp axis locking nut (L) loosened and straight clamp locking screw (T) tightened, distract to correct angular deformity. When correction complete, tighten clamp axis locking nut.

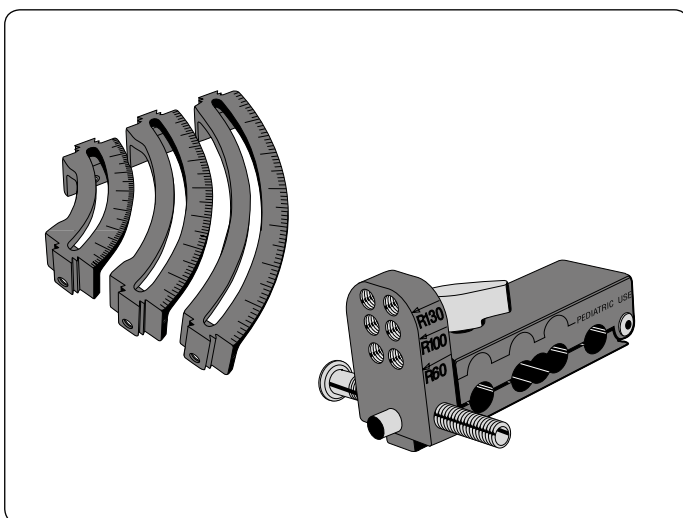


THE ACUTE CORRECTION TEMPLATES

Compatible with either adult or pediatric limb reconstruction system, they may be used to correct acutely an angular or rotational deformity, or combination of the two.

Angulation Templates

Allow correction in two planes. Two hinges on each clamp, one for alignment in coronal plane, the other in sagittal plane.



Rotational Templates

The template consists of two components: an arc and a template clamp.

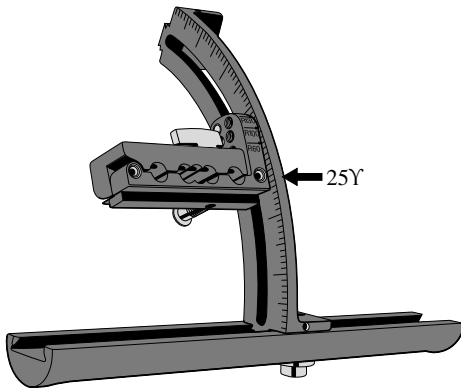
3 arc sizes for different sizes of limbs (60mm, 100mm, 130mm).

Example Application Showing Use of Angulation and Rotational Templates in a 20° Varus and 25° Internal Rotation Deformity.

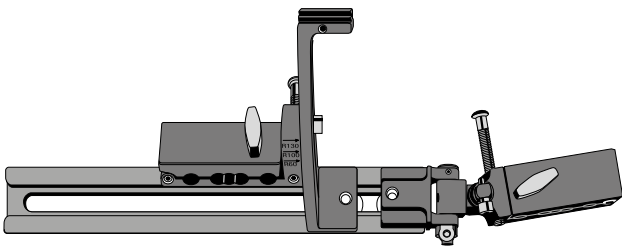
Choose correct size arc so that distance between rail and bone is equal to radius of arc selected.

Attach template clamp (*Use correct locking hole for arc size*).

Lock to arc at correct rotational position for screw insertion (in this case 25°).



Attach angulation template; adjust to reflect varus deformity; tighten hinge locking screws.

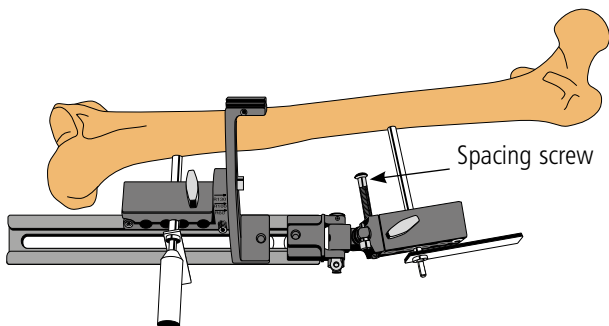


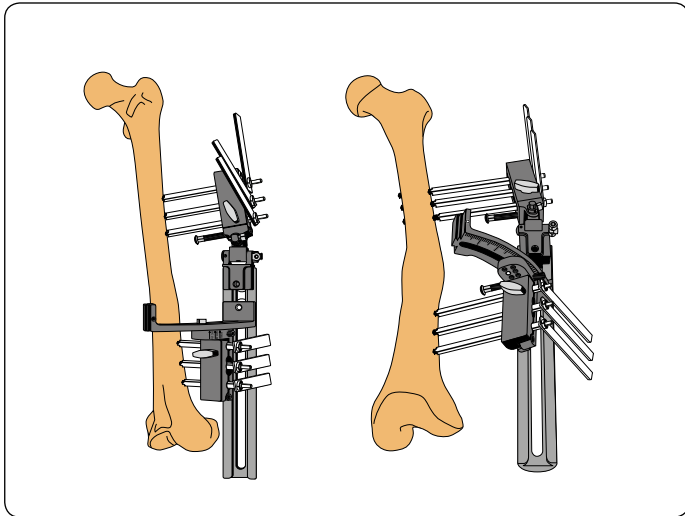
Hold rail 3-4 cm from skin; advance spacing screws in both clamp templates until they touch skin.

Insert screw at 90° to bone axis, just proximal to apex of deformity.

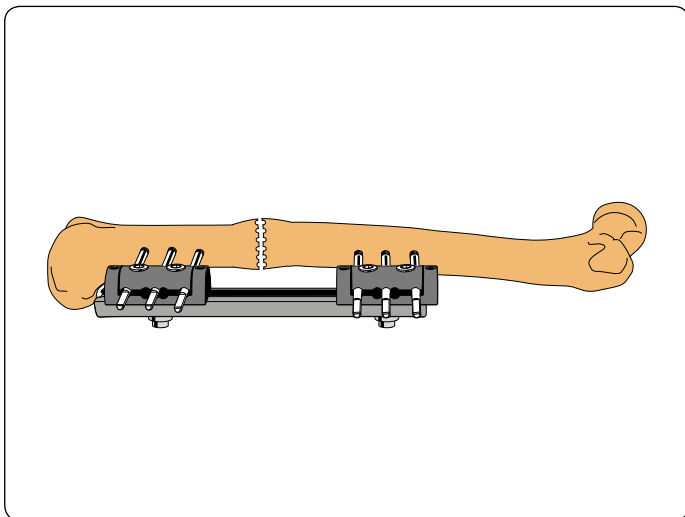
Insert trocar through screw guide in clamp template on arc, down to bone.

If template has been set up correctly, trocar will point towards center of bone, 90° to axis of distal femur. If okay, insert second screw. If not, adjust clamp until trocar points to center of bone.





Insert remaining screws, always 3 in each clamp in adults.



Perform osteotomy at apex of deformity; remove rail, and manipulate limb so that both pairs of bone screws are parallel.

Apply LRS rail with standard straight clamps, and tighten clamp locking screws.

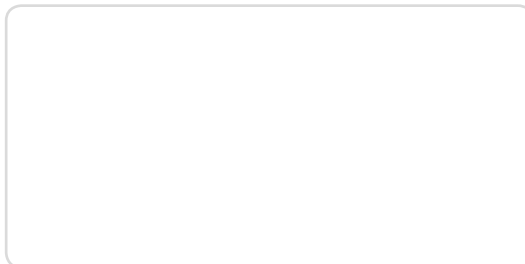
Electronic Instructions for use available at the website
<http://ifu.orthofix.it>

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