

SMALL BLUE D.A.F.

Operative Technique



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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please kindly refer to the product IFU PQEFS, 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.

DIAPHYSEAL FRACTURES TIBIA

Reduce the fracture as anatomically as possible, emphasizing rotational correction. A fixed reduction on a fracture table with a Steinman Pin is recommended.

Screw Insertion

Insert screws into the shortest or most difficult segment first, from the anterior or antero-medial aspect of the tibia. Make a 15-20mm incision so that the skin around each screw is not too tight (**Fig.1**). The underlying tissues also require broad dissection down to the bone.

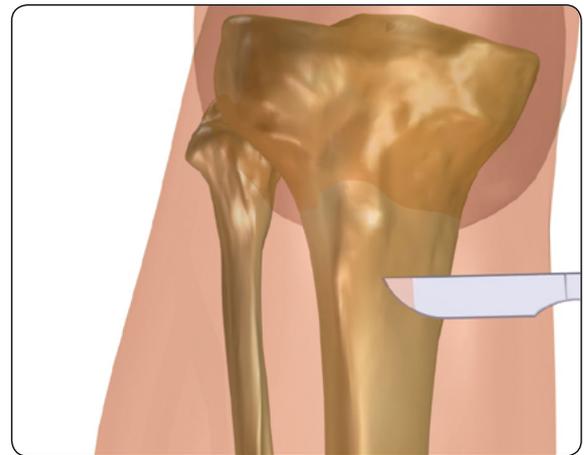


Fig. 1

Insert a screw guide perpendicular to the longitudinal axis of the bone.



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

Use a trocar to locate the midline by palpation. Keep the screw guide in contact with the cortex by gentle pressure, withdraw the trocar, and tap the screw guide lightly to anchor its distal end (**Fig.2**).

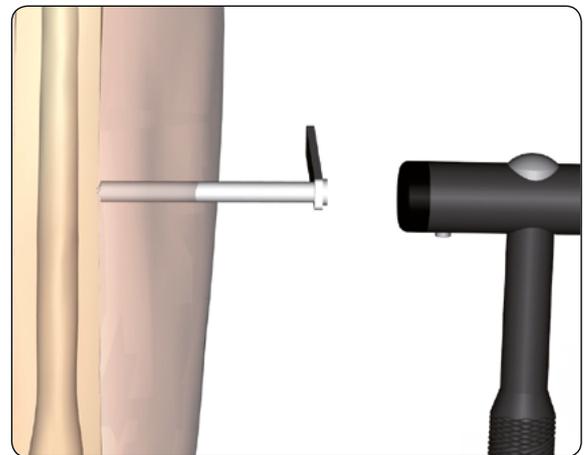


Fig. 2

If the placement of this screw is critical because it is close to a joint, the position can first be checked by inserting a 2mm Kirschner Wire. A screw guide can be centered over the wire by using a Ruland Wire Guide.



PRECAUTION: Wherever an implant wire or a guide wire is used to guide a cannulated reamer, drill bit or screw into position:

- a) The wire or guide wire should always be new.
- b) The wire should be checked before insertion to exclude any scratches or bends.
- c) During the introduction of any instrument or implant over a wire, the surgeon should screen the wire tip as continuously as possible to avoid inadvertently driving the wire further than intended.
- d) During each pass of the instrument or implant, the surgeon should check that there is no bony or other debris built up on the wire or inside the instrument or implant that might cause it to bind on the wire and push it forward.

Insert the correct drill guide into the screw guide (**Fig. 3**). Use screw guides for every screw insertion to minimize soft tissue trauma.

We recommend using screws with the correct thread length for the bone width at the insertion point. (Please see Manual PM 010 "General Application Instructions", Quick Reference Guide PG 200 "The XCaliber Bone Screws", Quick Reference Guide XC-1903-QR "The XCaliber Cylindrical Bone Screws - Insertion Technique" and Brochure PC OST "OsteoTite Bone Screws Technical Monograph" for additional information).

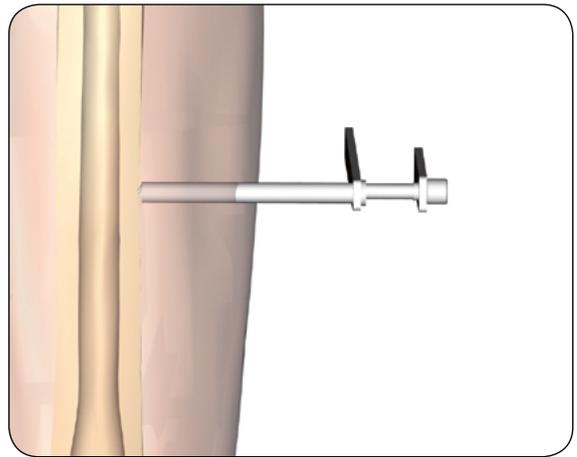


Fig. 3

Drill at 500-600 rpm through the first cortex with the correct drill bit and drill stop, checking that the drill bit is at right angles to the bone. The force applied to the drill should be firm and the drilling time as short as possible to avoid thermal damage. Stop at the second cortex, offset the stop collar by 5mm, and continue through the bone. Ensure that the drill bit completely penetrates the second cortex (**Fig. 4**). If a preliminary K-wire has been used, a cannulated drill bit can be used over the wire. Kirschner Wires that are used for this purpose and cannulated drill bits should never be reused.

 **WARNING:** If a cannulated drill bit is to be used for a second time on the same patient, the surgeon must check that the drill bit is free from obstruction by removing it from the power unit and passing a wire through it. Even when a cannulated drill bit is new, we recommend that a wire is passed through it prior to use to check that the lumen is free from obstruction.

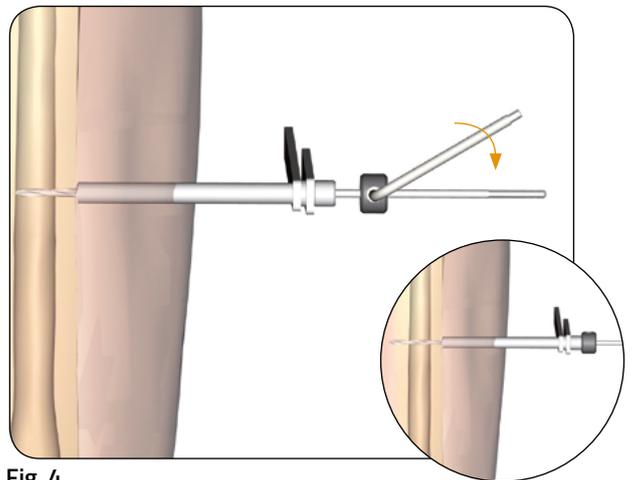


Fig. 4

Remove the drill bit and drill guide, keeping pressure on the handle of the screw guide. Insert the selected screw and turn it with the T-wrench until it reaches the second cortex. A further 5 or 6 half turns are then normally required to ensure that about 2mm of the screw protrudes beyond the second cortex (**Fig. 5**).

 **WARNING:** Do not excessively penetrate the second cortex with any type of screw 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 a conical screw once it has been inserted may cause it to become loose.

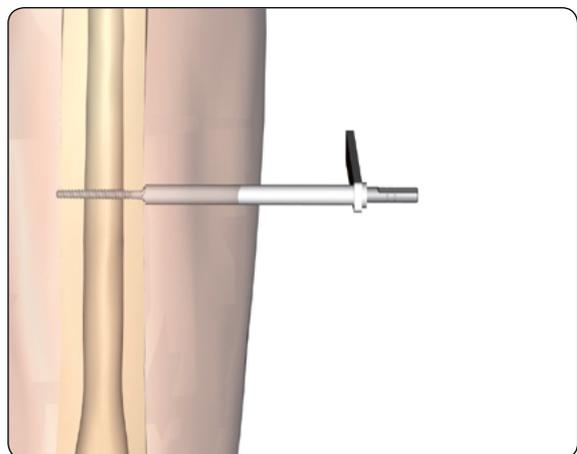


Fig. 5

Template Application

Leave the screw guide in position and apply the fixator template with the central body locking nut and cams loosened. Insert the three remaining screw guides, make the incisions, and insert them down to the bone (**Fig. 6**).

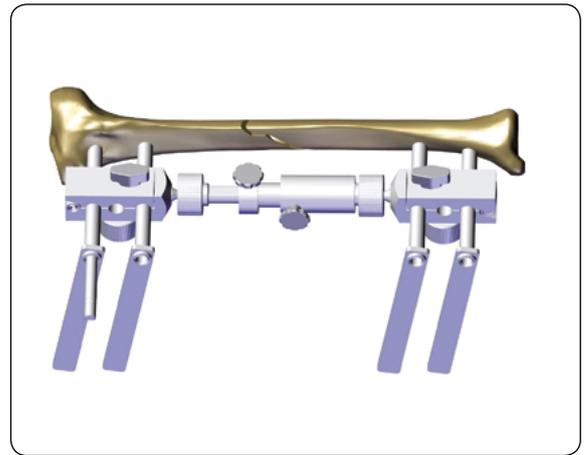


Fig. 6

Before screw insertion into the second bone fragment, adjust the template body to the correct length, making sure that it is neither completely closed nor fully open. This will allow for final reduction. Insert the first bone screw as before (**Fig. 7**).

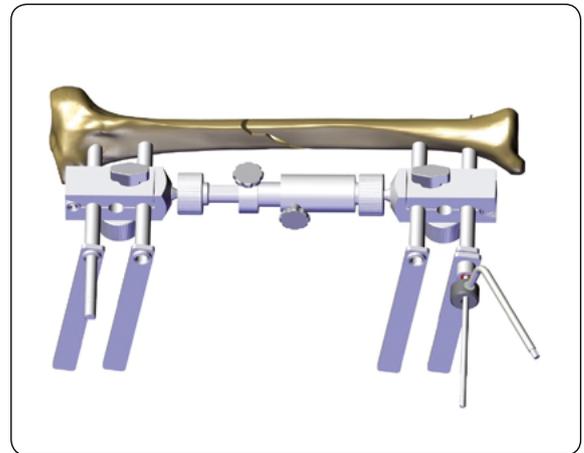


Fig. 7

Follow the same procedure to insert the two remaining bone screws. Loosen the clamp locking screws (**Fig. 8**) and remove the template and the screw guides.

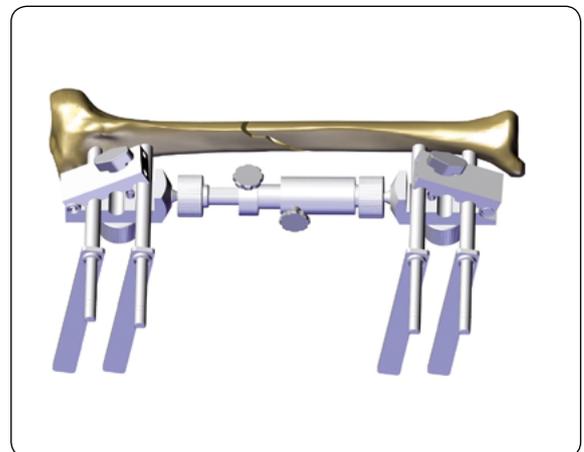


Fig. 8

Fixator Application

Apply the Small Blue DAF Fixator at least 2cm from the skin.



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 4cm from the bone, the use of 3 screws per clamp is advisable.

Align the body parallel to the major axis of the segment being treated. Fully tighten the clamp locking screws (**Fig. 9**).



WARNING: Axial displacement may occur if the body of the fixator is not in line with and parallel to the bone.



WARNING: Medial or lateral translation may occur if the body of the fixator is not placed parallel to the diaphysis.

Obtain final reduction with manipulation forceps (**Fig. 10**).

Hold the reduction in a good position while an assistant tightens the cams and the central body locking nut with an Allen Wrench (**Fig. 11**).

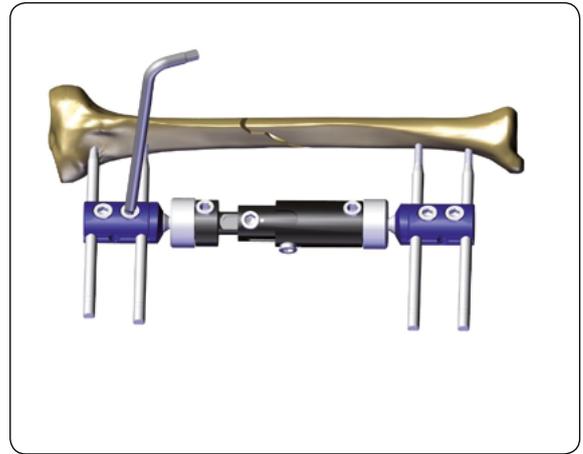


Fig. 9

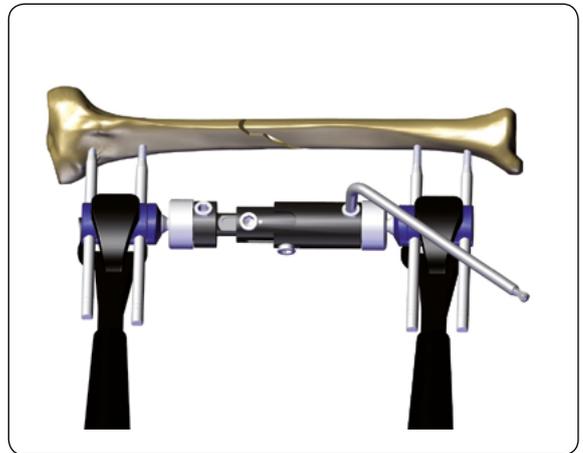


Fig. 10

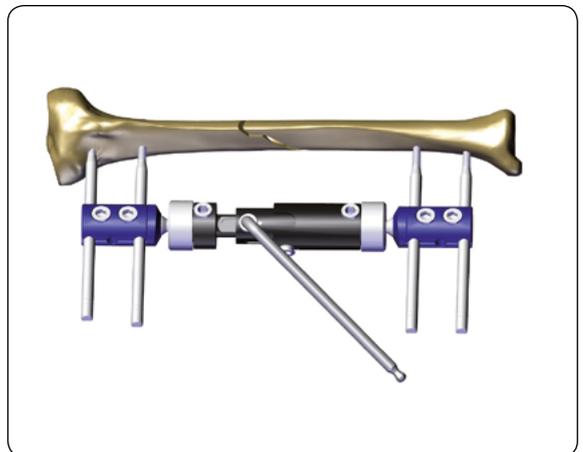


Fig. 11

Lock the cams definitively with the 5mm torque wrench until you hear a “click” indicating the correct torque (**Fig. 12**). Use the torque wrench only to tighten the cams, and never use it to loosen anything.

 **WARNING:** Any attempt to unlock the cam or any screw using the torque wrench will damage its gearing.

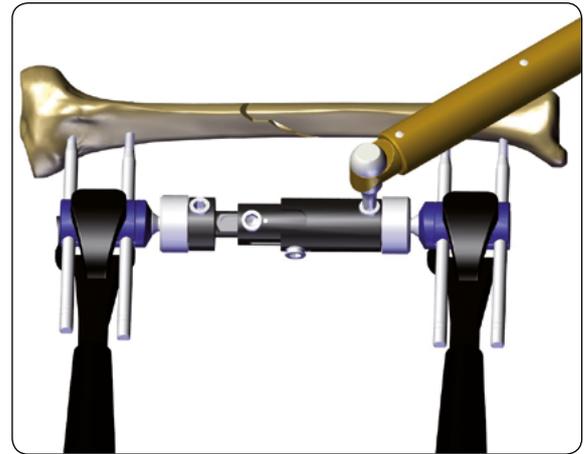


Fig. 12

With the Central Body Locking Nut loosened, compression or distraction can be achieved using the compression-distraction unit fitted into the cams.

 **WARNING:** For increased stability the compression-distraction unit may be applied to the fixator body and locked into place.

The Allen Wrench is used to turn the screw of compression-distraction unit either clockwise or counterclockwise (one full turn = 1mm) (**Fig. 13**).

 **WARNING:** Compression is never recommended in a fresh fracture.

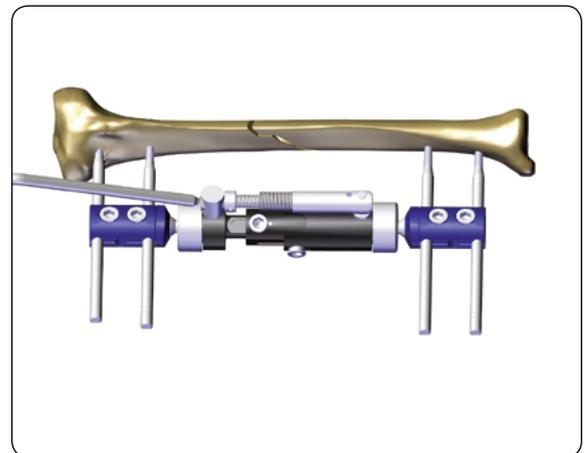


Fig. 13

Release any skin tension around the screws by extending the skin incision.

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

 **PRECAUTION:** The fracture site gap should be reassessed periodically during healing, and adjustments to the frame made as necessary. Persistent separation of the fracture ends may lead to delay in bone union.

DIAPHYSEAL FRACTURES FEMUR

Reduce the fracture approximately and any rotational displacement as completely as possible. Apply a Small Blue DAF Fixator, as described above, to the lateral aspect of the femur. Insert 6 screws, 3 in each clamp, using screw and drill guides and the fixator template. Position the second group of screws to allow the body of the fixator to be open a minimum of 1cm. Screws should never be less than 2cm from the fracture line. Obtain final reduction using manipulation forceps with the fixator in place. Lock the fixator as above, again using the 5mm torque wrench for the cams only (**Fig. 14**).



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



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DIAPHYSEAL FRACTURES HUMERUS

Reduce fracture approximately and any rotational displacement as completely as possible. Apply a Small Blue DAF Fixator, as described above, to the lateral aspect of the bone. Insert 4 screws, 2 in each clamp (at the maximum distance to guarantee stability), using screw and drill guides and the fixator template. Insert the most distal screw first, 1cm proximal to the lateral epicondyle. To avoid risk of damage to the radial nerve, use an open procedure. Position the proximal screws to allow the telescopic body of the fixator to be open a minimum of 1cm. Reduce and lock as before (**Fig. 15**).



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



PRECAUTION: The fracture site gap should be reassessed periodically during healing, and adjustments to the frame made as necessary. Persistent separation of the fracture ends may lead to delay in bone union.

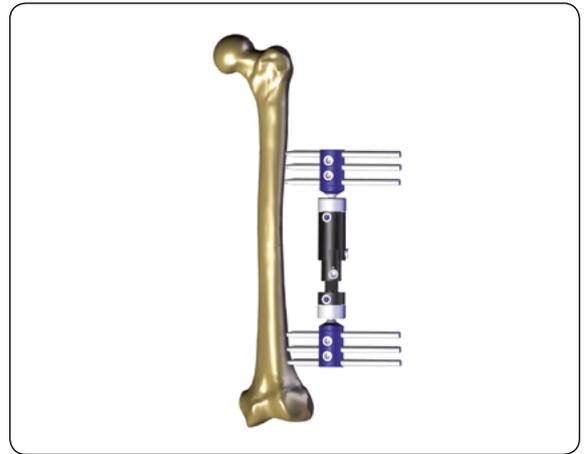


Fig. 14

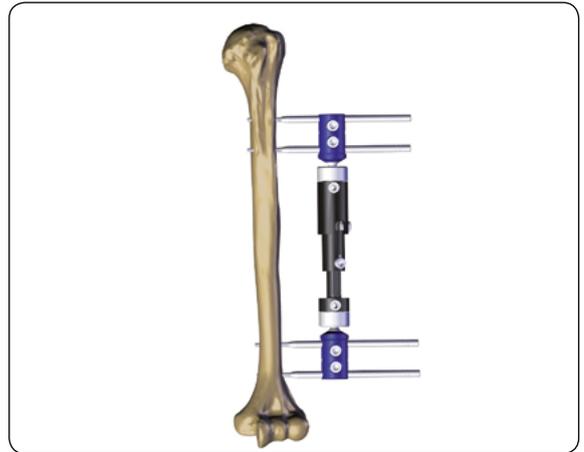


Fig. 15

PROXIMAL METAPHYSEAL FRACTURES TIBIA

Apply the Small Blue DAF Fixator (with the T clamp proximally and the straight clamp distally) antero-medially, using the fixator template as described above. Insert the most anterior proximal screw first, freehand, 2cm distal to the knee joint, and insert second proximal screw in 3rd seat of the clamp (Fig. 16).

Osteotite™ (HA-Coated) Bone Screws may be useful in this application.



Fig. 16

Insert the diaphyseal screws, again checking that the fixator body is not completely closed (Fig. 17).



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



PRECAUTION: The fracture site gap should be reassessed periodically during healing, and adjustments to the frame made as necessary. Persistent separation of the fracture ends may lead to delay in bone union.



Fig. 17

DISTAL METAPHYSEAL FRACTURES FEMUR

Apply the Small Blue DAF Fixator (with the T clamp distally and the straight clamp proximally) laterally, using the fixator template, as described above. Insert the most anterior distal screw first about 1cm behind the anterior edge of the lateral condyle, and insert the second proximal screw in the third seat of the clamp. Insert the diaphyseal screws, checking that the fixator body is not completely closed (Fig. 18).

Osteotite (HA-Coated) Bone Screws may be useful in this application.



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



PRECAUTION: The fracture site gap should be reassessed periodically during healing, and adjustments to the frame made as necessary. Persistent separation of the fracture ends may lead to delay in bone union.



Fig. 18

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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