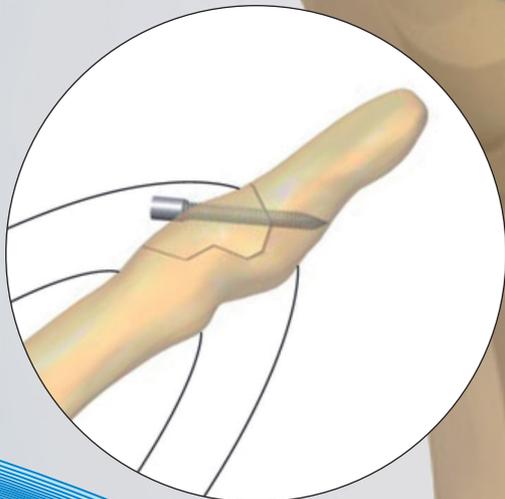


QUICK REFERENCE GUIDE

Fragment Fixation

System

One-Step Fracture Fixation



INTRODUCTION

The Fragment Fixation System (FFS) includes threaded wires and washers, and dedicated instrumentation. The wires have a three-edged tip similar to that of a K-wire, and a fine thread of uniform diameter, followed by a polished shaft of slightly greater diameter. If needed, the contact surface between the bone and the implant can be increased by the use of a washer. Washers are available in medium and large diameter. FFS Wires are available in three shaft diameter/ thread diameter combinations with different thread lengths. The total length of each wire is 120mm.

FFS can be used in upper and lower extremities. It allows securing small bone fragments, and can act as a joystick by exerting a compressive effect on insertion. Choose the appropriate implant according to the fracture pattern and the anatomical site. Select the diameter of FFS in relation to the size of the fragment and the length of the FFS in relation to the size of the main bone.

FEATURES AND BENEFITS

- All implants 120mm long in a variety of thread lengths cut to length after insertion.
- The proximal portion of each implant consists of a smooth shaft, the diameter of which is greater than that of the threaded section.
- The FFS Implants are drilled directly into the bone, and have a cylindrical thread that allows them to be backed out following insertion.
- Percutaneous insertion; no pre-drilling or pre-tapping required.
- Medium and large sizes can be combined with a washer to improve cortical contact.
- The chamfer at the intersection of the threaded portion and the smooth shaft functions to maintain fracture reduction.
- The FFS Implants combine the dimensions and simplicity of use of K-wires, with the security of fixation afforded by larger and less versatile screws.
- Implants have a three-sided trocar cutting tip and a finely machined threaded section, specially designed to guarantee good purchase in cancellous bone.
- Compression possible between fragments.
- Excellent stability guaranteed by fine thread and unique design.
- The compression of a lag screw with the simplicity of a K-wire.
- Simplicity saves operative time.

Please kindly refer to the product IFU PQFFS and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.



PRECAUTIONS: Correct selection of the implant model and size is extremely important.



PRECAUTIONS: Correct handling of the instrumentation and implant is extremely important and notching or scratching of the implants should be avoided, as these factors may produce internal stresses that may become a focus for possible implant breakage.

	Thread Diameter	Shaft Diameter
Small	1.2mm	1.5mm
Medium	1.6mm	2.0mm
Large	2.2mm	3.0mm

Determine the intended position of the implant before insertion. Insert the FFS Implant without pre-drilling or tapping. Do not bend the implant during insertion into the bone, since this might lead to breakage.



WARNING: Bending of the Fragment Fixation System Implant during insertion must be avoided, since this may lead to breakage of the implant.

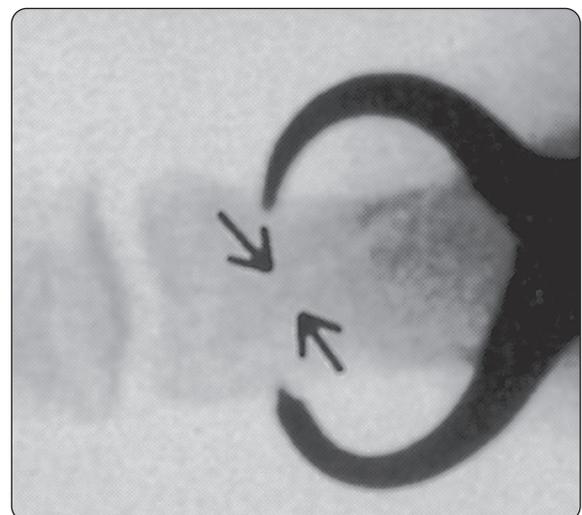
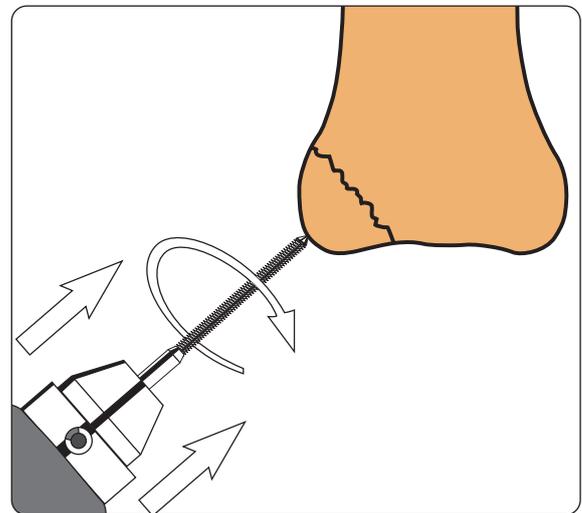


WARNING: Fracture distraction for any time should be avoided during the operation, and fractures should never be locked in distraction, since this may cause delayed union and/or compartment syndrome.

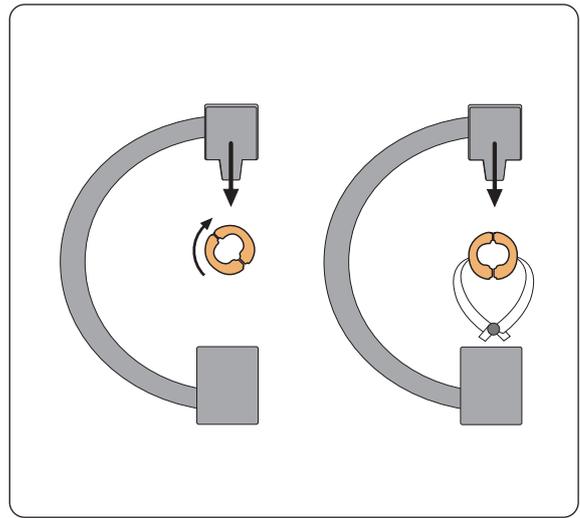


PRECAUTIONS: When the chamfer of the FFS Implant is close to the cortex, the speed of insertion must be reduced. It is recommended to complete insertion by hand.

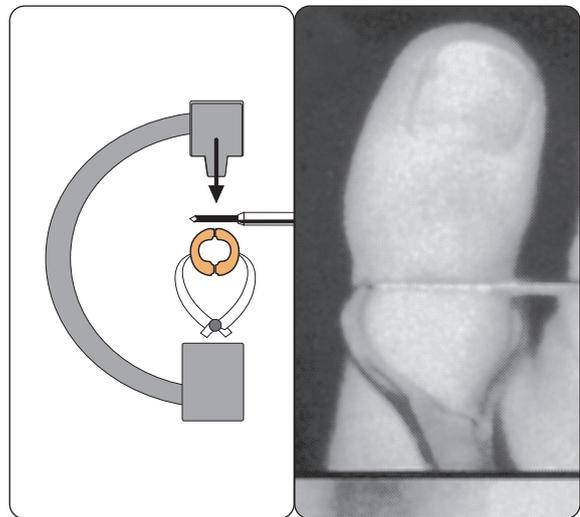
Reduce the fracture anatomically. Use forceps where possible for reduction and interfragmentary compression.



Turn the extremity until the X-ray beam is aligned with the fracture gap, and verify reduction.



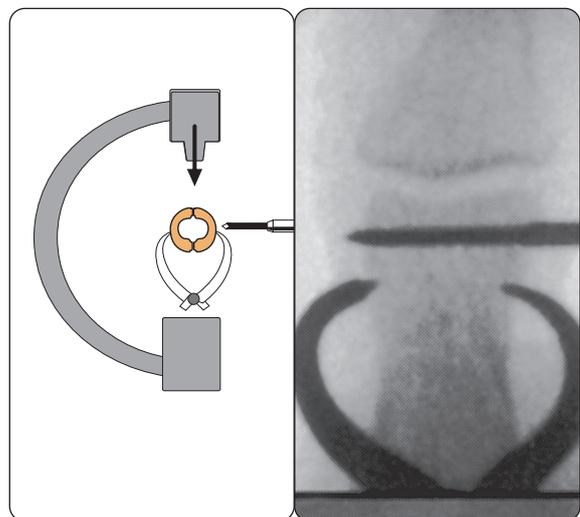
Measure the implant thread length required pre-operatively on the X-ray or determine it by overlaying an implant of adequate size.



Insert the implant percutaneously, perpendicular to the X-ray beam, until the chamfer meets the near cortex.



PRECAUTIONS: After insertion, ensure correct positioning of the implants under image intensification.



A second implant enhances rotational stability. Cut the implants just above the chamfer. Whenever possible, the cut end should be covered with skin. In the fingers and toes, where this is not possible, leave the end exposed and cover with a sterile dressing. Leave the FFS Implants in place until fracture healing, and remove them when necessary using the extractor.



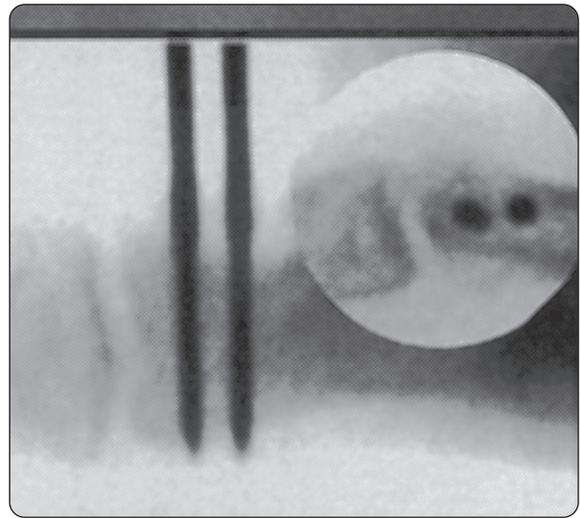
WARNING: If callus is slow to develop, other measures may be required to promote its formation, such as dynamisation of the implant, a bone graft, or exchanging the implant for a larger one.



PRECAUTIONS: Careful monitoring of the progress of healing must be undertaken in all patients.



WARNING: Any fixation device may break if subjected to the increased loading caused by delayed or non-union.

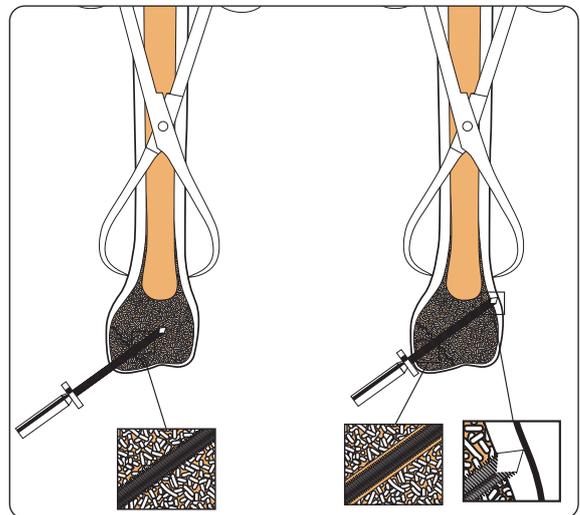


COMPRESSION EFFECT

The compression effect can be obtained in two ways.

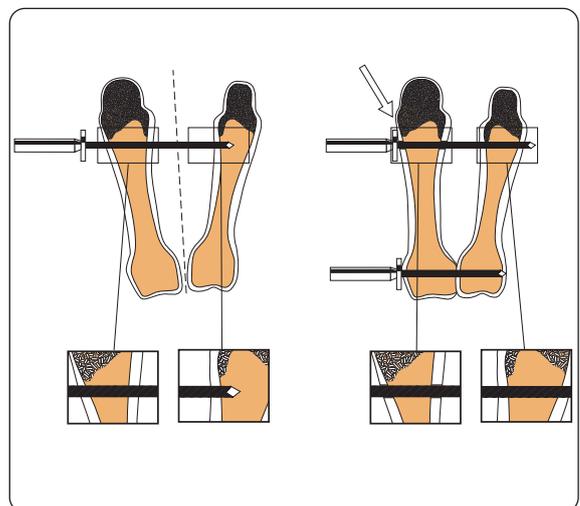
If, for example, a bone fragment at the base of a phalanx requires reattachment, the implant is inserted in an oblique direction starting at the cancellous base of the bone with the tip directed towards the contralateral cortex.

When the tip reaches the contralateral cortex, the speed of insertion of the implant must be reduced. As the implant meets the resistance of the hard cortical bone, the thread makes several revolutions without advancing initially, leading to a gliding hole proximally and a threaded hole distally. When the chamfer and washer reach the bone, the two fragments will be compressed together. Insertion should be stopped at this point.



PRECAUTIONS: When the chamfer of the FFS implant is close to the cortex, the speed of insertion must be reduced.

In the example shown, an inter-metacarpal dislocation resulted in widening of the space between adjacent metacarpal heads. The FFS Implant is first drilled into the near metacarpal producing a threaded hole. On reaching the far metacarpal it also produces a threaded hole. At the moment the washer reaches the near metacarpal cortex, the FFS revolves without advancing, thus producing a gliding hole in the near metacarpal. This allows the two metacarpal heads to approximate.

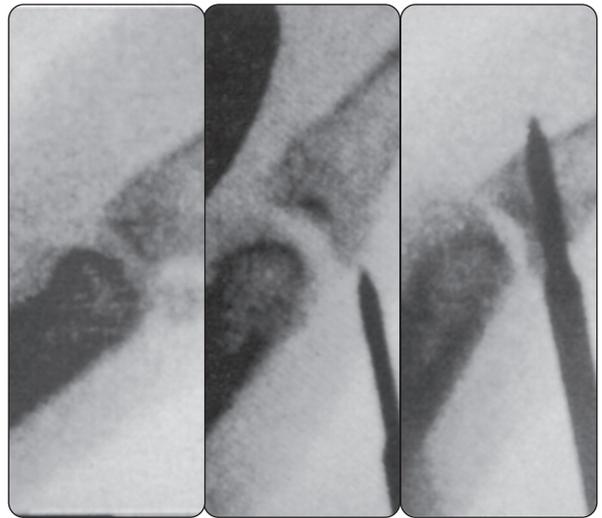


APPLICATION IN THE UPPER EXTREMITY

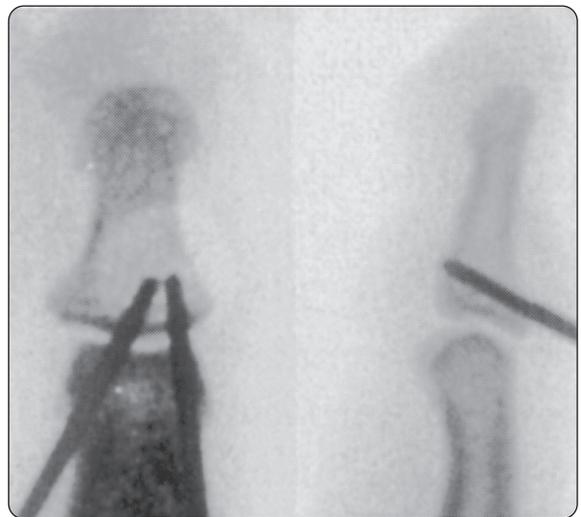
Hand

Bush Fractures

Place the tip of the implant on the fragment percutaneously, with gently increasing pressure until the fracture gap disappears. Advance it slowly until the chamfer reaches the near cortex. Weber or other bone forceps may be used for reduction.

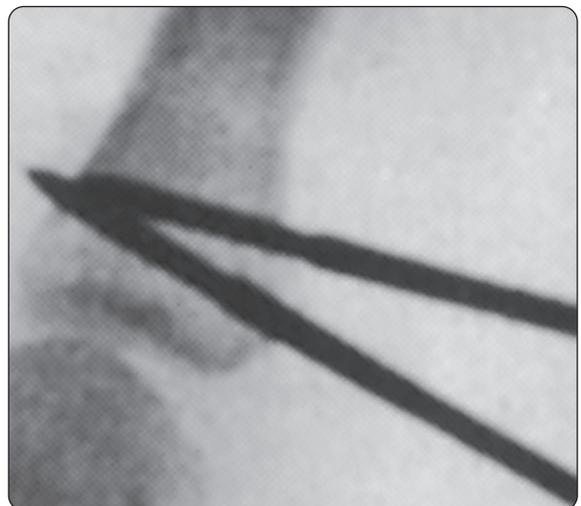


A second implant may be inserted in a slightly converging fashion.



Fractures at the Base of the First Phalanx

Insert two implants and cut close to the chamfer leaving 2-3mm outside the bone.



DISTAL RADIUS

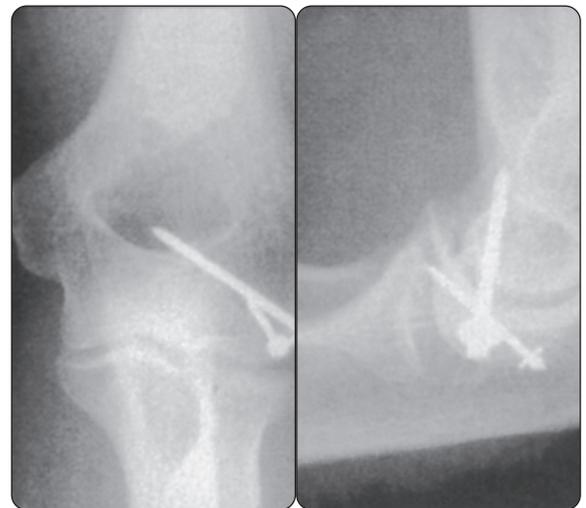
In comminuted fractures, following application of the external fixator, insert two FFS Implants in a crossed fashion to prevent secondary loss of radial length and angulation. In this case the concomitant ulnar fracture was treated with a single FFS Implant.



ELBOW

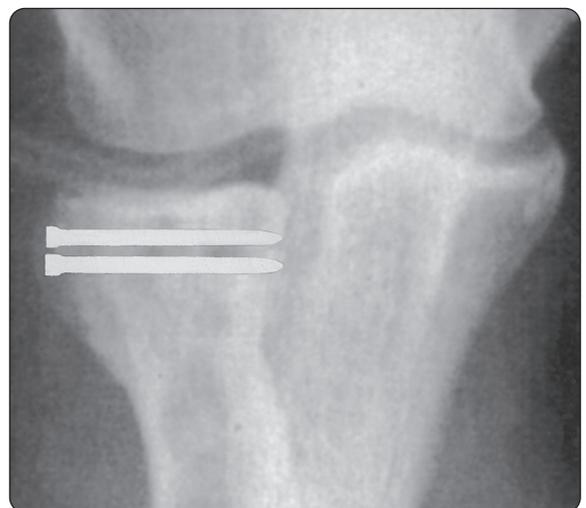
Humeral Epicondyle Fractures

After open reduction, insert the implants, both with washers.



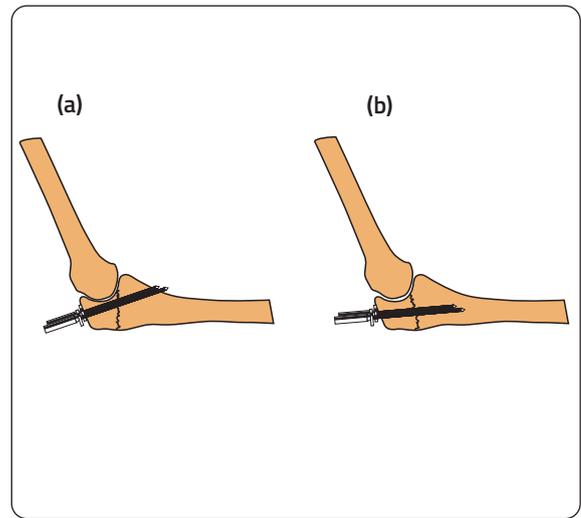
Radial Head Fractures

Reconstruct the radial head using implants without a washer. Drill the implant into a fragment and use it as a joystick to manipulate it into its anatomical position. Then advance the implant slowly into the adjacent bone. Cut the implant shaft as close as possible to the cartilage-covered surface of the radial head.



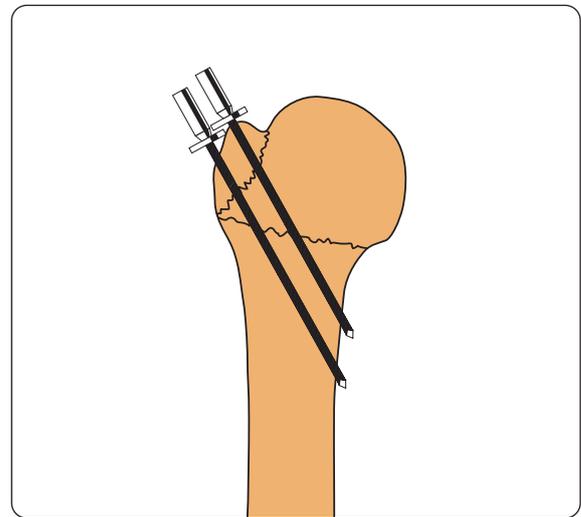
Olecranon Fractures

Use implants with washers. Expose the fracture site through a dorsal approach, and reduce it anatomically. Starting at the tip of the olecranon, insert two FFS Implants parallel to one another or in a slightly v-shaped configuration across the fracture line. In elderly patients with osteoporosis, anchor both implants in the ventral cortex of the ulna (a). In younger patients, the implants may be securely anchored in the cancellous bone and penetration of the contralateral cortex may not be necessary (b).



Proximal Humerus

Stabilise a subcapital fracture combined with one of the greater tuberosity using two FFS Implants with washers.

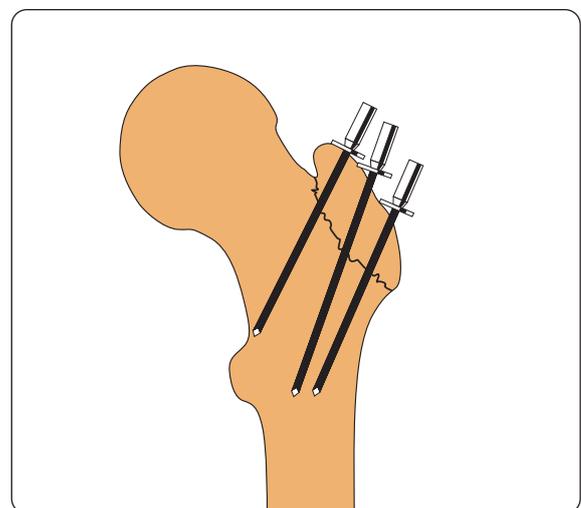


APPLICATION IN THE LOWER EXTREMITY

Hip and Knee Joints

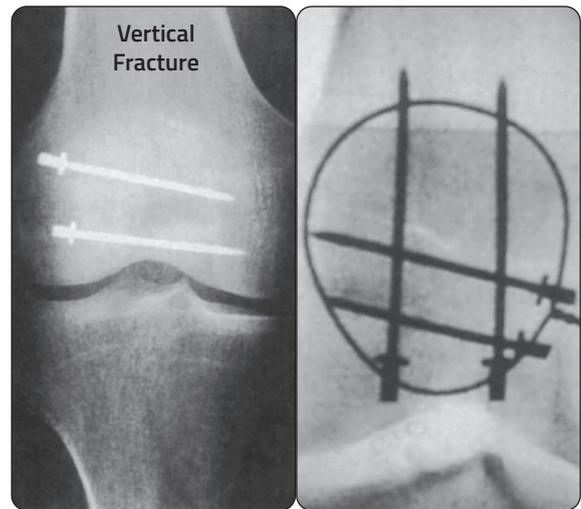
Fractures of the Greater Trochanter

Except in the presence of severe osteoporosis, it is possible to reattach the greater trochanter securely using three implants with washers. Use additional tension band wiring when needed, eg, if the bone quality is poor.



Fractures of the Patella

Reduce the fragments with bone forceps and insert the FFS Implants. After wound healing, early passive physiotherapy is recommended to achieve minimum knee flexion of 90°. In case of poor bone quality or in the presence of more complex fractures, use an additional tension band wire.



Tibia

Proximal Tibia

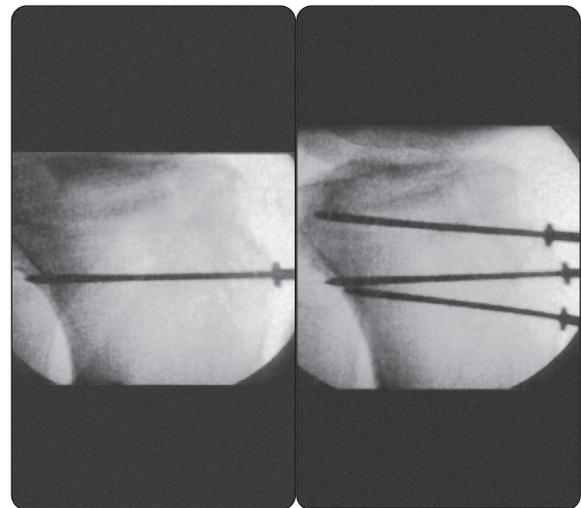
In avulsion of the tibial tuberosity, insert the implants with compression (penetrate the second cortex and use washers).

In monocondylar fractures insert two implants percutaneously under image intensification, parallel to the joint line in subchondral bone.



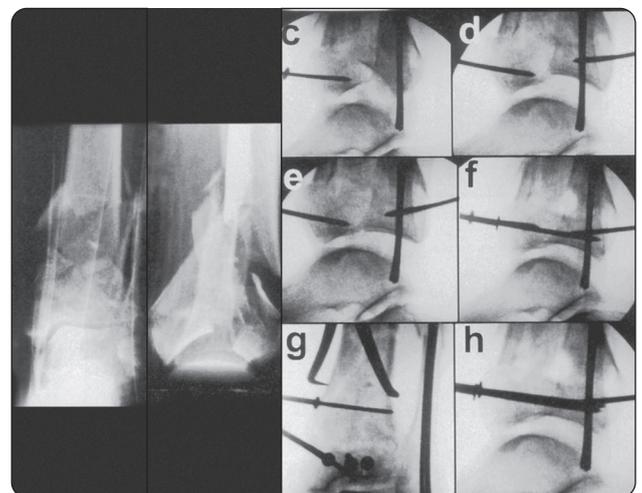
PRECAUTIONS: During and after insertion, ensure correct positioning of the implants under image intensification.

In more comminuted tibial plateau fractures, open reduction and internal or external fixation is advisable. In these cases, the FFS Implants are an additional measure to achieve joint congruency and support the reduction with the implants placed in subchondral bone.



Distal Tibia

Insert the implants percutaneously or with an open approach and use them as joysticks to reduce the main joint-building fragments. After achieving anatomical reduction, insert the implants fully.

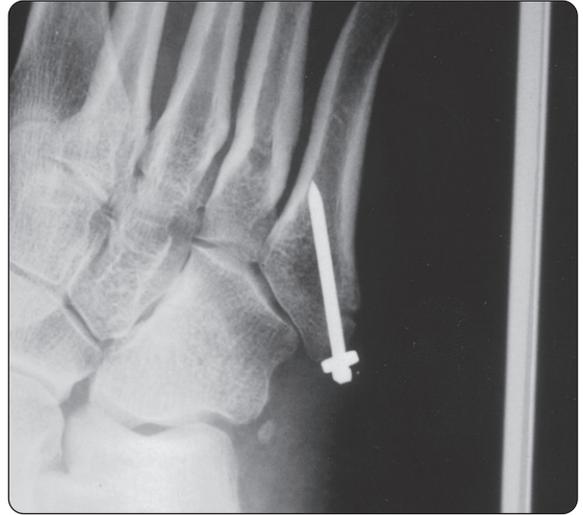


Foot

Metatarsal and Phalangeal Fractures

Use FFS Implants in metatarsals and proximal phalanges.

In displaced fractures, use open reduction.



IMPLANT REMOVAL

Perform a small incision and remove the FFS with the help of the extractor. There are two extractor sizes: one for small/medium implants (W1001) and one for large implants (W1002). Select the appropriate one and turn the knob on the top of the extractor counter-clockwise to engage the FFS; a 3mm Allen Key (10012) may also be used to tighten this knob.

Once engaged, use the extractor to unscrew the FFS.



Please refer to the “Instructions for Use” supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information 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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