

OPERATIVE TECHNIQUE

# Gotfried PC.C.P.™

System



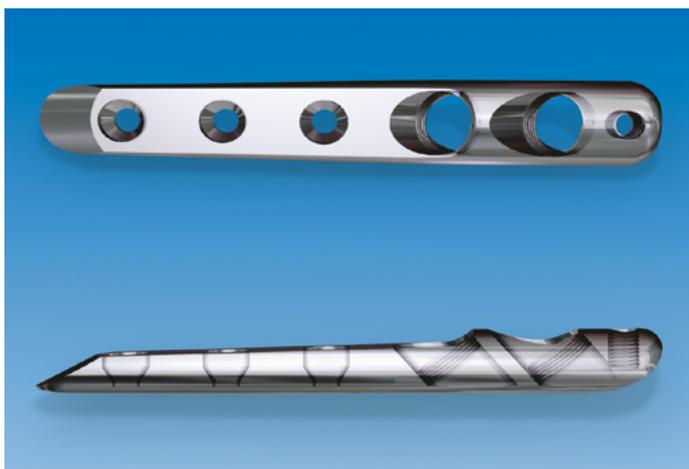
# Gotfried PC.C.P.<sup>™</sup>

## System

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Operative Technique Contributing Surgeon:  
Dr. Y. Gotfried, MD, MS



## EQUIPMENT REQUIRED

### Gotfried PC.C.P Plate 181000

This plate only comes in one size. The head will be connected to the introducer, while the chisel-like end will pass through the tissues and on the surface of the periosteum. There are two oblique holes at the head for the femoral neck screws, and three more distal holes for the shaft screws.



### Gotfried PC.C.P Neck Screws

Two are used with each plate; available lengths vary from 90mm to 140mm in 10mm increments. Screws are telescopic with a barrel portion (a), which is screwed into the plate, and a self-tapping screw portion. The latter has a hexagonal recess (b), for the neck Screwdriver to advance the screw into the femoral neck. It also has an additional recess (c), which accepts the threaded part of the neck Screwdriver for drawing the screw (and with it the proximal fragment) backwards for fracture compression.

- 182090 Total length 90mm
- 182100 Total length 100mm
- 182110 Total length 110mm
- 182120 Total length 120mm
- 182130 Total length 130mm
- 182140 Total length 140mm



### Gotfried PC.C.P Shaft Screws

These are self-tapping screws ranging in length from 31mm to 46mm in 3mm increments. A threaded recess and two grooves at the screw head are used to attach the screws to the shaft Screwdriver.

- 183031 Total length 31mm
- 183034 Total length 34mm
- 183037 Total length 37mm
- 183040 Total length 40mm
- 183043 Total length 43mm
- 183046 Total length 46mm

**Gotfried PC.C.P Instrument Tray Kit empty  
209000 can accommodate:**

PartNo.	Description	Quant.
184000	Neck Screwdriver	1
185000Q	Shaft Screwdriver	1
186000Q	7.0mm Drill Bit	1
187000Q	9.3mm Drill Bit	1
188000Q	Shaft Step Drill	2
189000Q	Main Guide	1
190000	Quick Coupler	1
191000	Introducer	1
192000	Butterfly Screw	1
193000Q	Butterfly Pin	1
194000	Bolt	2
195000	Main Sleeve	1
196000	Neck First Sleeve	1
197000	Neck Second Sleeve	1
198000	Trocar - Neck	1
199000	Gauge Aluminium	1
200000	Impactor	1
201200	Aiming Guide	1
202000	Bone Hook Adapter	1
203000	Shaft Sleeve	1
204000Q	Trocar - Shaft	1
205000	Depth Gauge	1
206000	Skin Retractor	1
207000	Bone Hook	1
208000	Fixation Wire	1
210000	PC.C.P Template	1

**Supplementary Equipment**

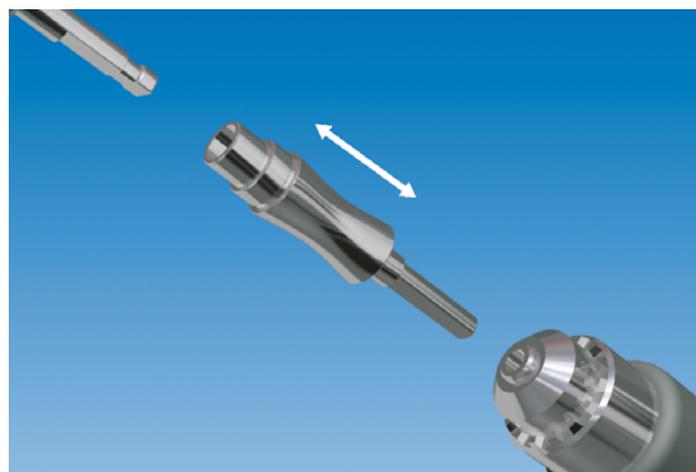
- PORD™ 110000
- No. 10 Scalpel Blade\*
- 18 Gauge Spinal Needle\*
- Metzenbaum Scissors\*
- Mallet\*

\* not provided by Orthofix

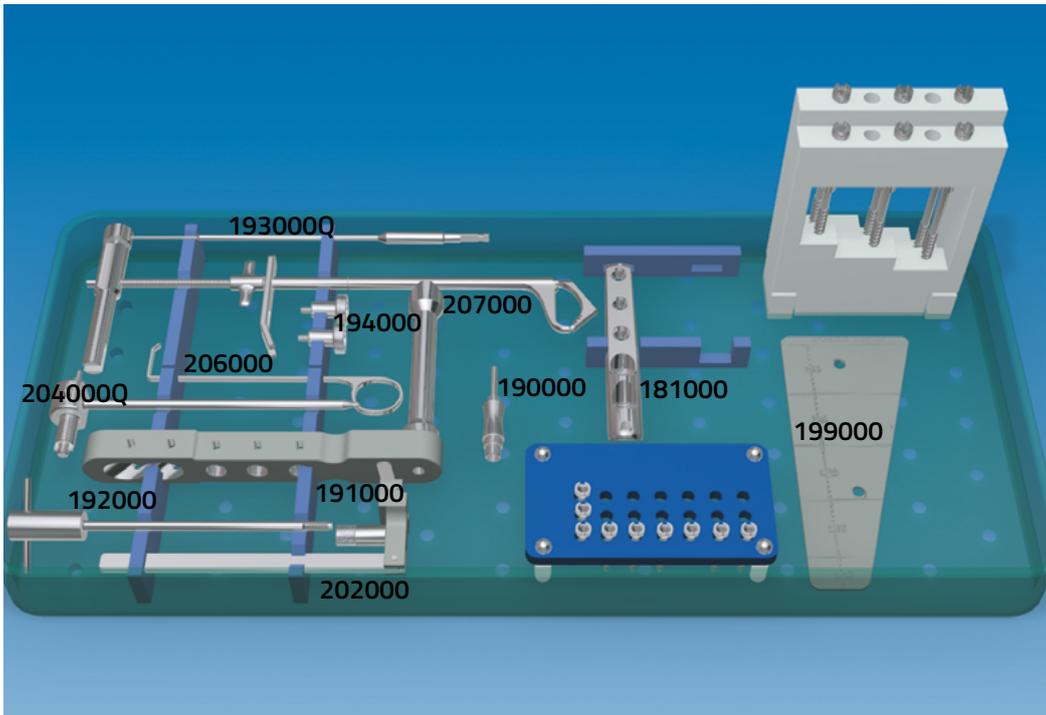
**210000 PC.C.P Template**



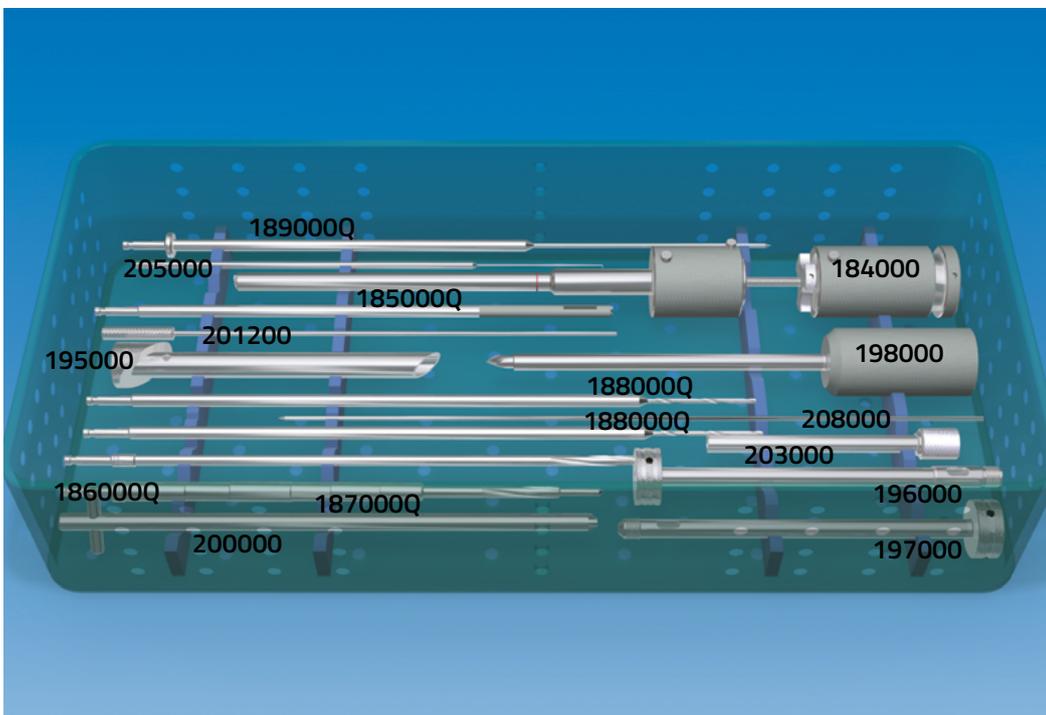
**190000 Quick Coupler**



Gotfried PC.C.P Instrument Case



Upper Tray

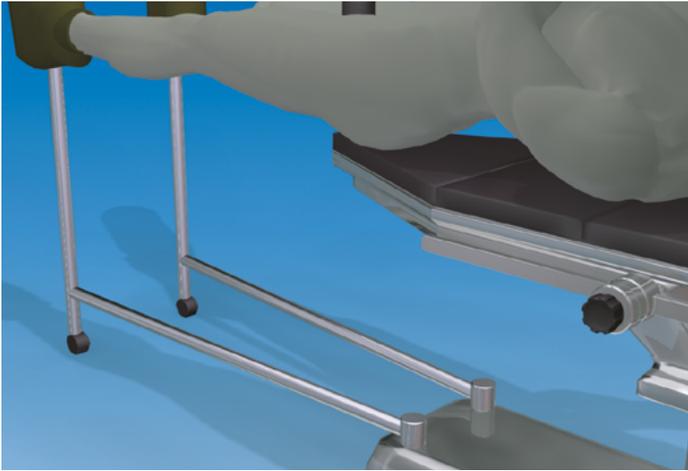


Lower Tray

## **CLEANING AND STERILIZATION**

Orthofix supplies the P.C.C.P Plate, neck screws, shaft screws and instruments NONSTERILE. They therefore must be cleaned before use, as described for new products. The whole cleaning, disinfection and sterilisation cycle must be followed before each use, as described in the product Instructions For Use PQPCP.

Disassemble the Neck Screwdriver and Bone Hook for thorough cleaning and disinfection prior to sterilization.



## OPERATIVE TECHNIQUE

### Fracture Reduction in the Frontal Plane

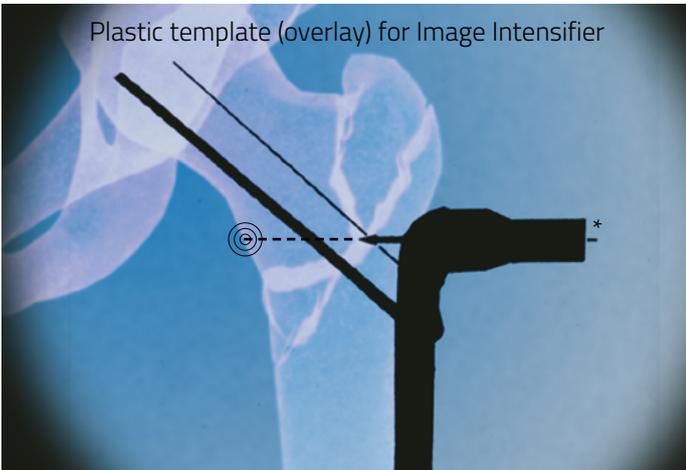
The patient is placed on a fracture table, and initial reduction obtained by traction under image intensification.



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

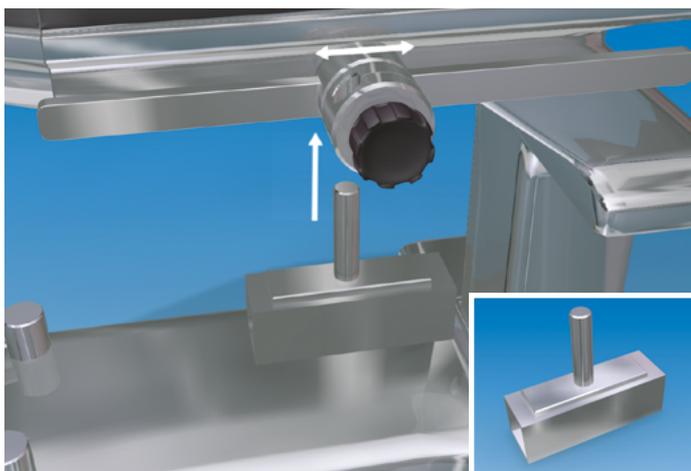


**PRECAUTION:** The Gotfried PC.C.P. should only be used if there is a proper fracture table available, so that the fracture can be held in a stable reduced position. Fracture distraction for any time should be avoided during the operation, and fractures should never be locked in distraction, since this may cause delayed union.



With the image of the proximal portion of the femur on the screen, the plastic template (210000) with a picture of the device in situ, is placed over it. Traction is then adjusted if necessary, to arrive at a neck-shaft angle of 135 degrees and to ensure that the more distal neck screw will lie 2-3mm above the femoral calcar.

In addition, the arrow on the template indicates a target point on the medial side of the femur in the region of the lesser trochanter. The target point will be adjacent to the lesser trochanter in a variable position, and is in line with a straight continuation of the introducer connector arm (marked with an asterisk). Marking this position and bringing the introducer connector arm in line with it will ensure that the plate is in the correct position on the AP view.



### Posterior Reduction of the Fracture

Any posterior sagging at the fracture site should now be corrected and maintained using the dedicated Posterior Reduction (PORD™). This device is easily attached to most fracture tables.

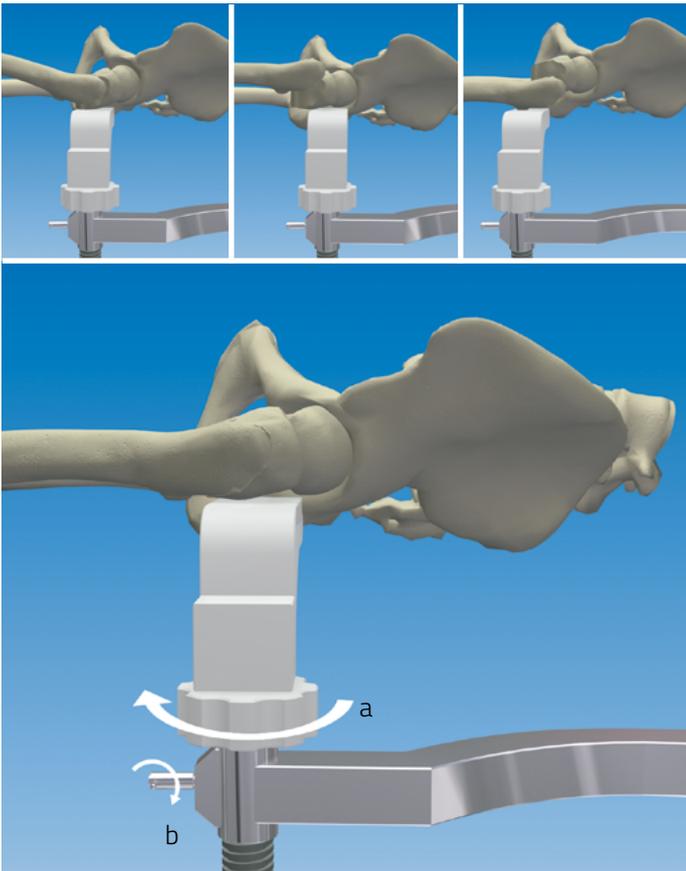
Position the patient on the fracture table. Slide the Clark Attachment onto the side rail of the fracture table. Insert the vertical post of the Box Bracket into the Clark Attachment from beneath and tighten the clamp on the post so that the bracket is held securely.



Assemble the PORD™ in the following way: Slide the Horizontal Bar through the Box Bracket with its curved portion facing the fracture table. This curved section is designed to accept the C-arm of the Image Intensifier.

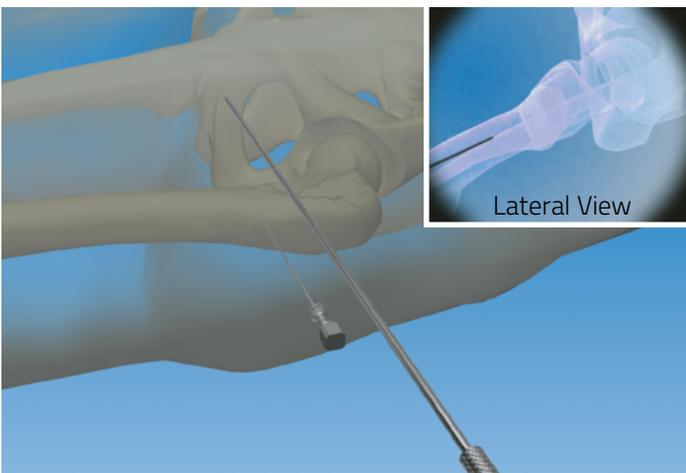


The Screw Jack of the Limb Support should be seated completely within the housing of the Horizontal Bar with the Nut turned so that it lies just beneath the Radiolucent Ledge.



The Limb Support is positioned beneath that portion of the fracture that requires elevating.

The correct position of the support is confirmed on the AP view (the shadow of the support can be seen). Again using the lateral view, the Limb Support is raised by turning the Nut (a) until exact posterior reduction has been achieved. The position of the Support is now maintained by tightening the Lug Screw on the housing (b). There is tendency for the Limb Support to rotate when its position is being adjusted, due to the conical cross-section of the thigh. It should therefore be held firmly during this procedure, and while tightening the Lug Screw. The PORD - will now remain in position throughout surgery. The PORD is then draped and therefore does not require sterilization. It may be cleaned following surgery using a detergent solution and dried thoroughly.

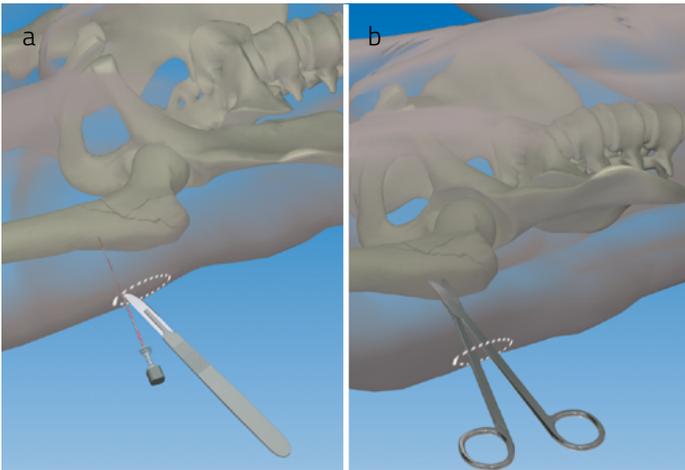


### Operative Procedure

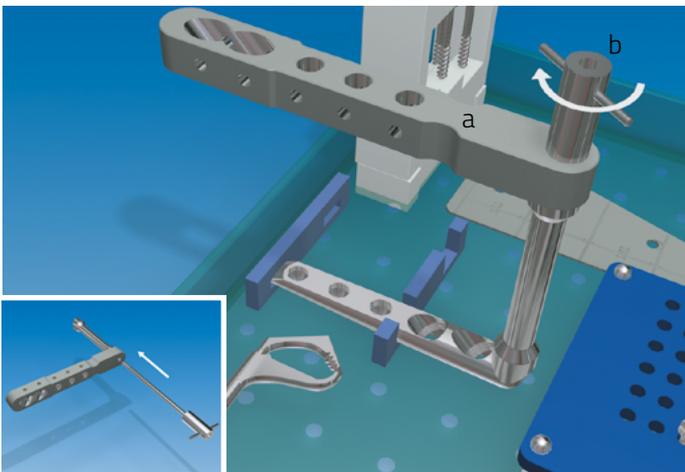
The patient is prepped and draped in the normal manner. The Aiming Guide is now placed on the anterior surface of the thigh, to coincide with the position of the arrow on the plastic template (usually at the upper border of the lesser trochanter). An 18 gauge spinal needle is now inserted into the thigh immediately beneath the Aiming Guide, at the level of the center of the femoral shaft while palpating the anterior and posterior shaft border. Correct central positioning of the needle must be confirmed with a lateral image on the Image Intensifier and any adjustments in its position made at this stage.



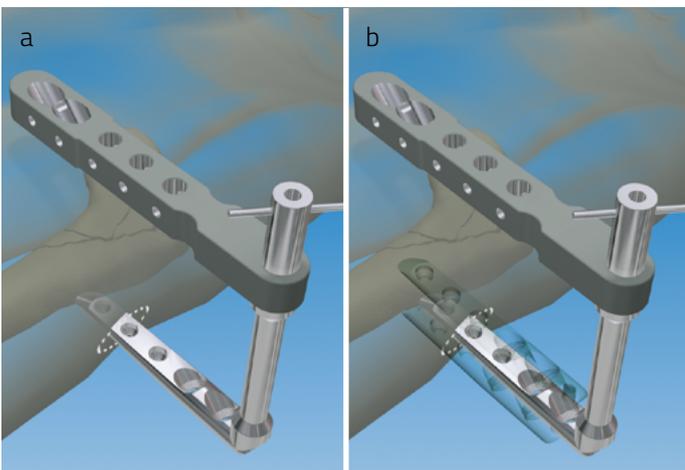
**PRECAUTION:** During and after insertion of the implants, ensure their correct positioning under image intensification.



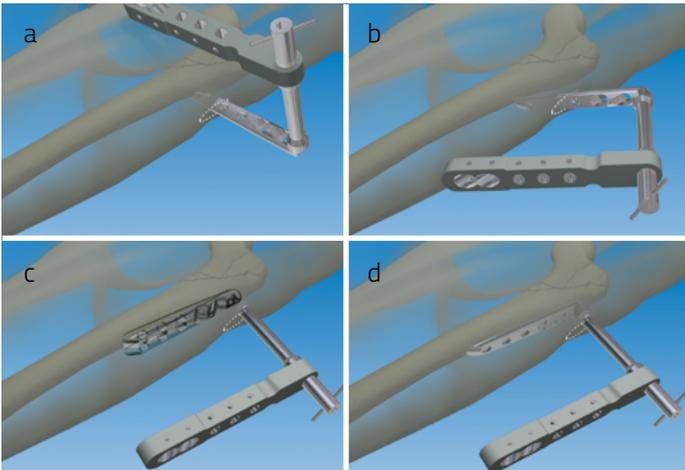
While the needle is in position, using a No.10 scalpel blade, make a 2 cm longitudinal skin incision proximal to the needle. This incision should pass through the skin and fascia only, but not through the underlying soft tissues. The deep tissues are now separated by blunt dissection down to the bone surface using Metzenbaum Scissors.



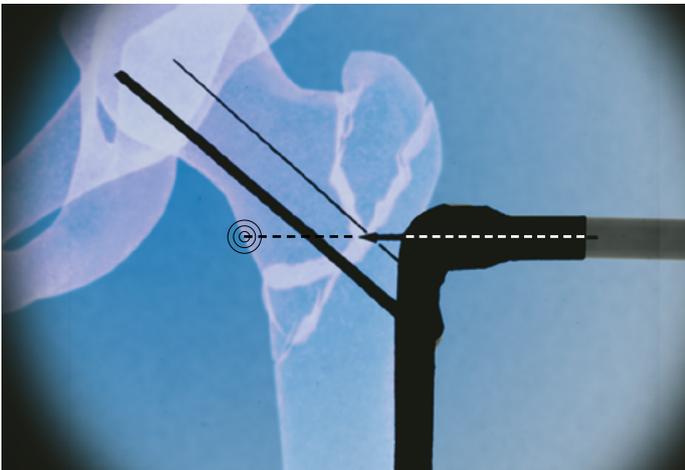
Take the introducer (191000) (a) and align it with the plate. The Butterfly Screw (192000) (b) is now passed through the cylinder at the end of the Introducer (191000), and screwed into the hole in the blunt end (head) of the plate, ensuring that the body of the Introducer is parallel to the plate. This should be a "no-touch" technique. Initial connection is performed while the plate is still in the sterilization box, with final tightening following its removal.



The plate is inserted into the incision at right angles to the shaft of the femur (a). The vastus lateralis muscle is now split, using the chisel end of the plate, which is used to identify the anterior and posterior surfaces of the femur (b). If some soft tissue remains on the femoral shaft, a scalpel blade is used to dissect down to the bone.



With its chisel end over the center of the femoral shaft (a), the plate is now turned so that its long axis is essentially parallel to the femoral shaft (b), with the chisel end directed slightly anteriorly to take account of the anterior bowing of the bone. Using the chisel end as a blade, the plate is now advanced along the bone using small antero-posterior movements (c), in a plane of cleavage between the vastus lateralis muscle and the periosteum, which is preserved. Note that the plate must be deep under the muscle (d).

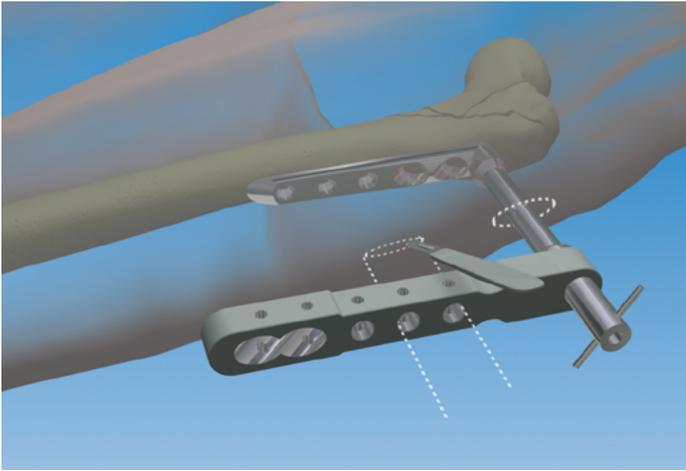


At this point correct positioning of the plate is confirmed with an AP view on the Image Intensifier, using the plastic template over the screen. Bringing the introducer connector arm in line with the target point will position the plate in the correct AP position.

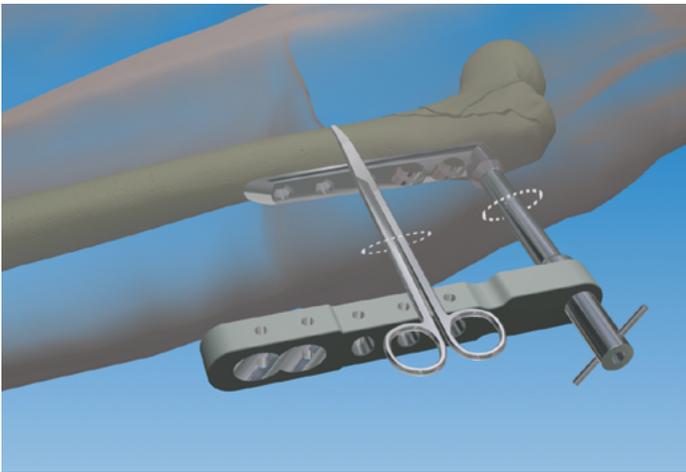


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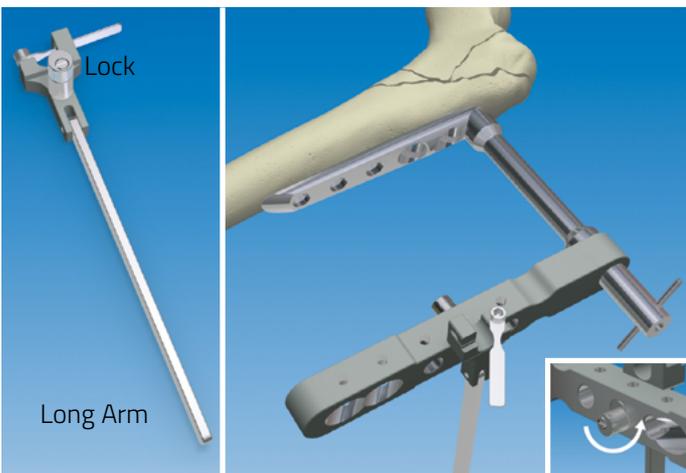
Correct AP position: The plate is in contact with and exactly parallel to the long axis of the femur, and when introduced, the distal (first) femoral neck screw will lie 2-3mm above the calcar (= calcar notch line). Corrections and adjustments can be made at this point to ensure that the desired position of the plate is obtained. A lateral image is of no value at this stage, since as yet, there is no reference point.



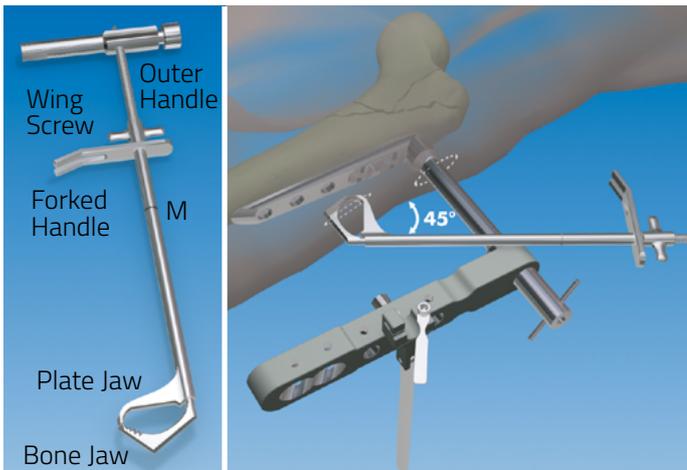
The second incision is now made. The scalpel is inserted through the middle hole of the introducer down to the skin, and a mark made on the skin. The scalpel is removed and used to make an incision, 2 cm in length, extending from the level of the distal margin of the middle shaft screw hole to the proximal margin of the proximal hole of the introducer. As before, this incision passes through skin and fascia only. The Metzenbaum Scissors are again used for blunt dissection of the tissues down to the plate.



The Metzenbaum Scissors with blades closed are now brought to the anterior surface of the femoral shaft and moved from side to side to separate the tissues from the bone in preparation for insertion of the bone hook. Particular attention must be paid to this procedure to ensure easy insertion of the bone hook.



The bone hook adaptor (202000) is now inserted through the middle vertical hole of the introducer and secured in place by tightening its knurled knob.



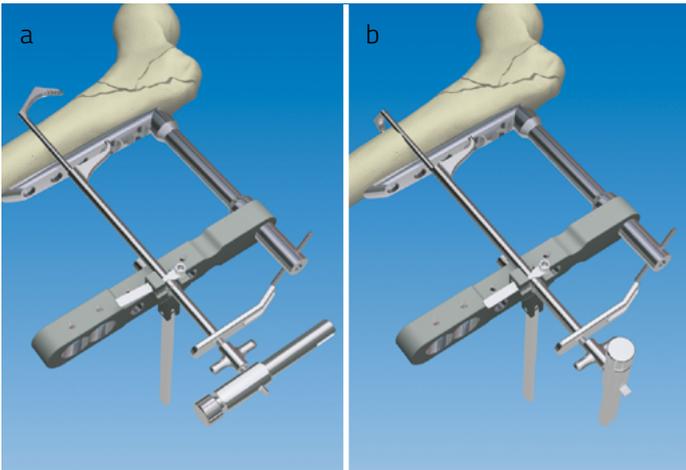
The bone hook (207000) has two jaws, a distal (bone) jaw that is curved to accept the medial aspect of the femur, and a flat proximal (plate) jaw to accept the plate. The hook is inserted through the second, distal incision, with its jaws closed. It is introduced in the frontal plane at 45 degrees to the femoral shaft so that the short cutting front edge of the bone jaw will enter the incision first.



Once within the incision, the bone hook is turned so that it is at 90 degrees to the shaft of the femur in the frontal plane, and advanced into the wound, keeping the handle (and therefore the jaws) parallel to the introducer. The bone hook is now locked to the bone hook adaptor in this position. The correct AP position of the plate is confirmed with image intensification at this stage to ensure that its position has not been disturbed. (lock and look).



The wing screw on the bone hook is now unscrewed fully. The outer handle of the bone hook can now be advanced with turning movements to push the distal (bone) jaw medially, anterior to the femoral shaft. It should be noted, however, that the outer handle can only engage the bone jaw shaft when both are in the same plane. This is an important feature of the device since it provides information on the exact orientation of the bone jaw within the wound.



The bone jaw only is now pushed medially (a) and turned downwards (b) through 90 degrees to grasp the femur firmly, keeping the jaw in contact with the bone throughout. This can be accomplished without the need for an X-ray. The Orientation of the handle shows the position of the jaw.



The plate jaw handle is now withdrawn until the M-line just disappears within the bone hook adaptor. This indicates that the plate jaw has cleared the plate; it is now rotated downwards through 90 degrees so that it can grasp it. Both bone hook handles are now stabilized with the long arm of the bone hook adaptor (a). The jaws of the bone hook are now slightly tightened with the wing screw.



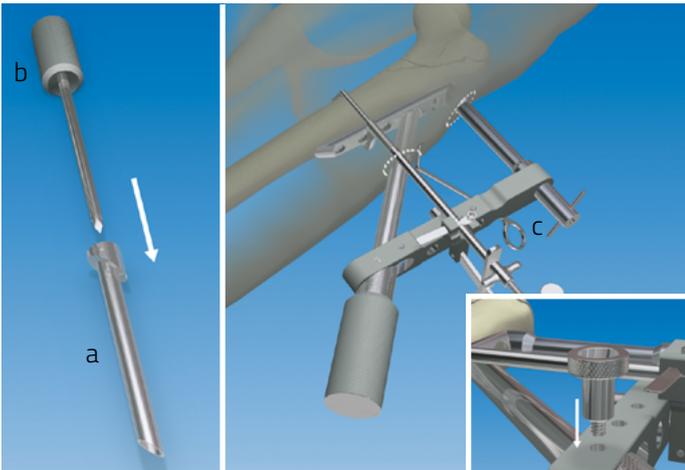
The position of the plate is now checked under lateral image intensification.



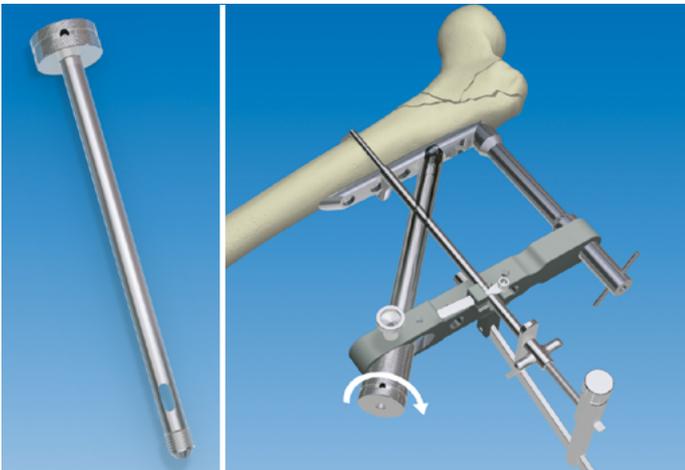
**PRECAUTION:** During and after insertion of the implants, ensure their correct positioning under image intensification.

If it is correct, the head of the plate will be in line with the femoral neck and the tail of the plate will lie along the femoral shaft. If a lateral view indicates that correction is needed, this can be made by twisting movements of the head and tail of the plate (the bone hook pivots) or by pulling the plate posteriorly (the bone hook glides and maintains the AP position). Check the AP position.

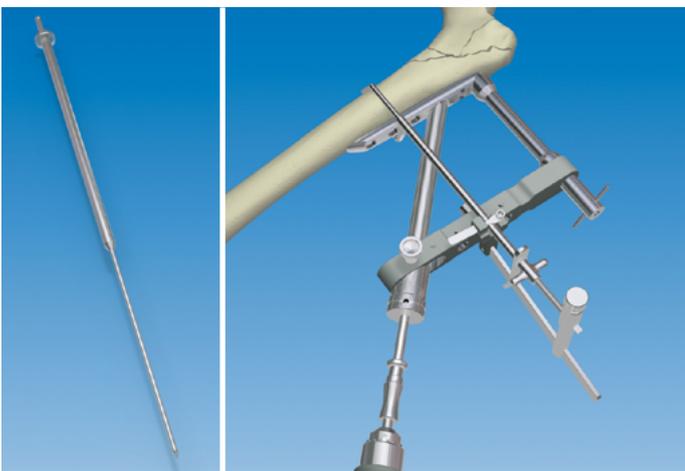
When both the AP and lateral position of the plate is satisfactory, the jaws of the bone hook are finally tightened with the wing screw to clamp the plate firmly to the bone.



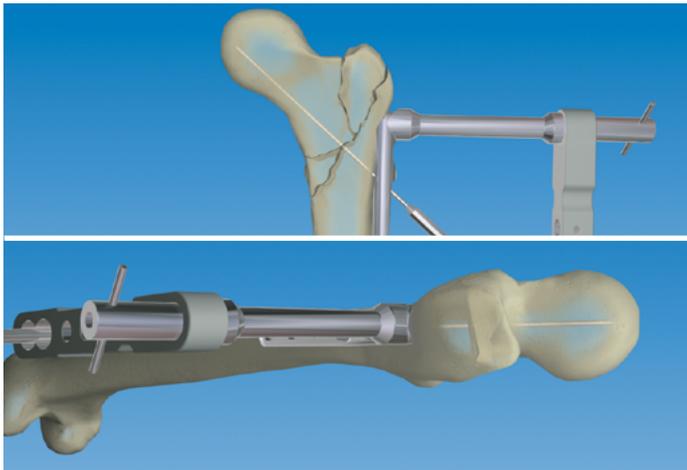
The main sleeve (195000) (a) and neck trocar (198000) (b) are now introduced through the most distal oblique hole of the introducer. This process is facilitated using the skin retractor (c) provided. The main sleeve is now locked into position with a bolt (d) inserted through the introducer. The trocar is withdrawn.



The first neck sleeve (196000) is identified by a single circumferential line around the head. It is inserted into the main sleeve and screwed into the plate. Any difficulty in achieving this may be due to soft tissue interposition, in which case the neck sleeve should be removed and the neck trocar reinserted and turned around to clear a path to the plate. The first neck sleeve is then reintroduced.



The Main Guide (189000Q) is now inserted into the first sleeve and drilled into the bone.



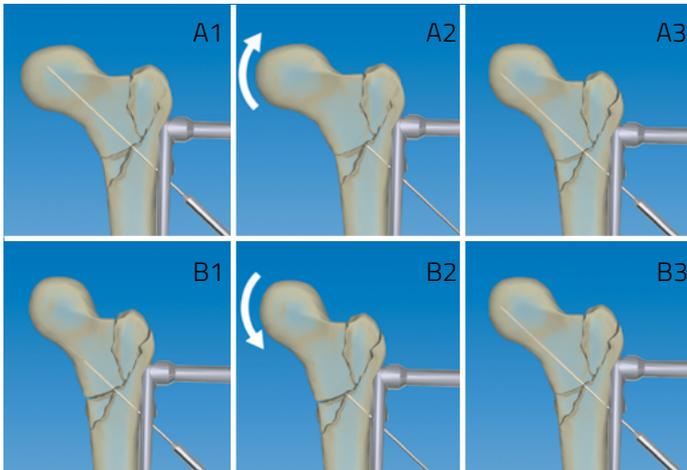
The position of the Main Guide is now monitored with AP and lateral views on the image intensifier.



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The AP view should show that it lies 2-3mm above the calcar; the lateral should show that it lies within the middle third of the femoral neck. The Main Guide is then further advanced to a point approximately 3-5mm from the articular surface.

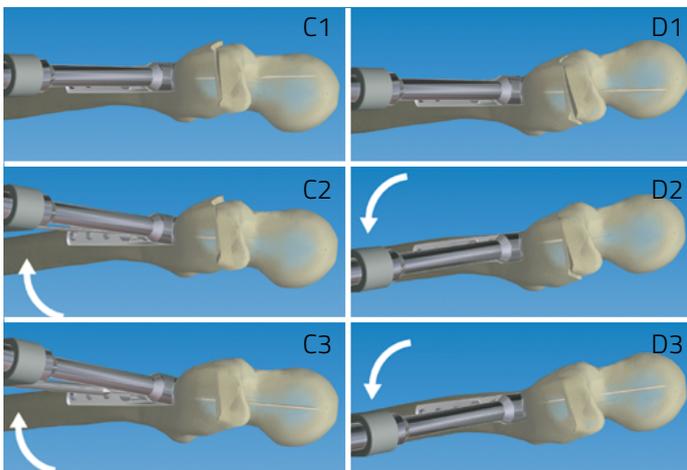
If any adjustment in the AP position is needed, the Main Guide can be withdrawn to a point just distal to the fracture line, and fracture table traction reduced or increased slightly (adding more varus or valgus) so that when reinserted, the Main Guide will adopt the correct position. This is an acceptable procedure where minor adjustments are required; if more major adjustments are needed, the plate may need to be moved up or down.



#### Reduction adjustments

Fig A (AP view): Fracture is reduced in excessive varus; A1: Main Guide misplaced because of excessive varus; A2: Main Guide withdrawn distal to the fracture line and fracture table traction increased to correct the position; A3: Main Guide advanced again and now in the correct position.

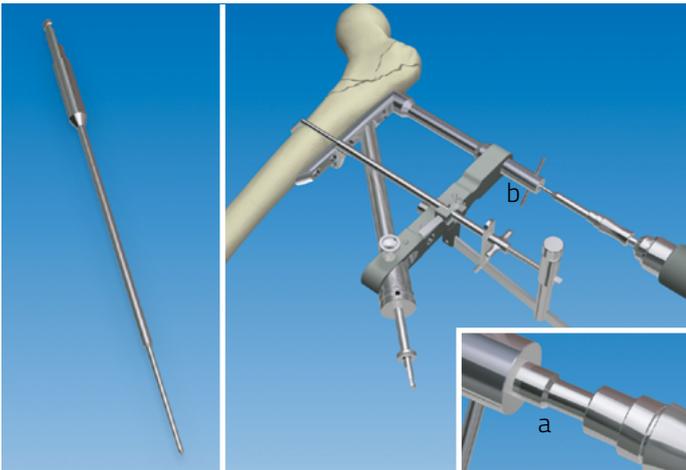
Fig B (AP view): Fracture is reduced in excessive valgus; B1: Main Guide misplaced because of excessive valgus; B2: Main Guide withdrawn distal to the fracture line and fracture table traction reduced to correct the position; B3: Main Guide advanced again and now in the correct position.



Corrections in the lateral view can be made by moving the introducer up or down, bringing the Main Guide more anteriorly or more posteriorly as required.

Fig C (lateral view): C1: Main Guide is too anterior (although the plate head is in the correct position); C2: Main Guide is withdrawn distal to the fracture line and the introducer lifted; C3: Keeping the introducer lifted, the Main Guide is advanced again and is now in the correct position.

Fig D (lateral view): D1: Main Guide is too posterior; D2: Main Guide is withdrawn distal to the fracture line and the introducer lowered; D3: Keeping the introducer lowered, the Main Guide is advanced again and is now in the correct position.



Once the position of the Main Guide is correct on both AP and lateral views, the butterfly pin (193000Q) is inserted into the butterfly screw and drilled into the bone, all the way to the stop (a). This provides two point fixation of the plate to the femoral shaft.

With a very unstable fracture, additional stabilization may be provided by means of a fixation wire, which is inserted through one of the accessory holes (b) in the introducer for a distance of 2-3mm into the acetabulum. This must be done under lateral image intensification.



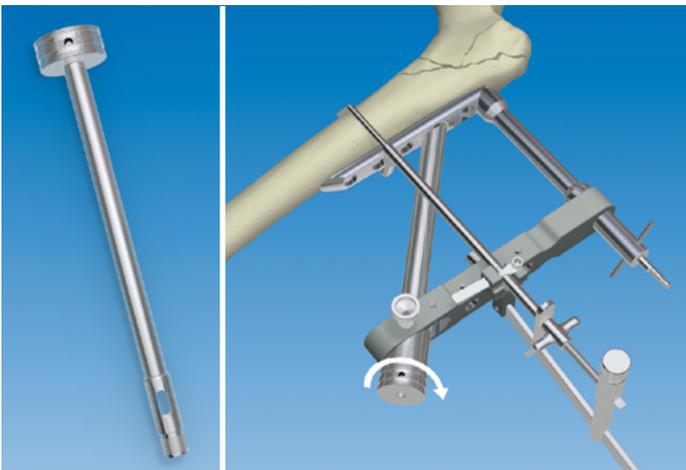
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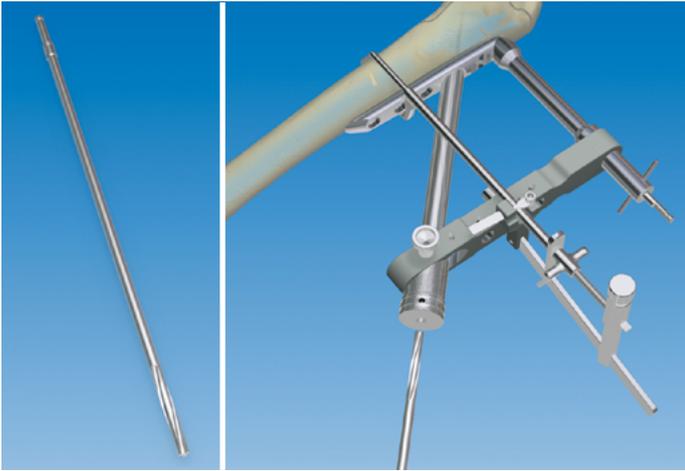
**WARNING:** The Gotfried PC.C.P. should not be used if the fracture is open or if the overlying skin is damaged as there is a risk of infection. In these cases, external fixation is preferable.



The length of Main Guide remaining outside, between its shoulder and the first neck sleeve, is a measure of the length of the neck screw required. This can be measured as shown, using the gauge (199000) with its square edge adjacent to the head of the first neck sleeve, and the oblique edge against the shoulder. The space over which the projecting portion of the Main Guide lies is marked with the length of screw required.



The Main Guide and first neck sleeve are now removed, and the second neck sleeve (197000) (identified by two circumferential lines around the head) introduced into the main sleeve and screwed to the plate.



The 7mm drill bit (186000Q) is now inserted into the second neck sleeve and drilled up to its stop. The direction of drilling should follow the corrected position of the Main Guide. This should be monitored under lateral image intensification. The 7mm drill bit and the second neck sleeve are now withdrawn.



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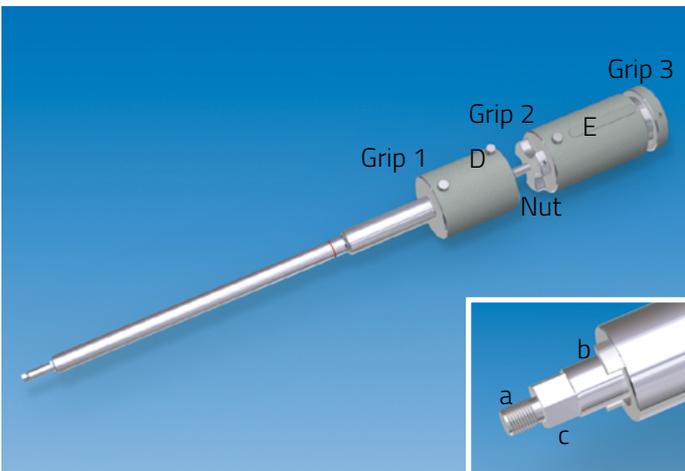


The 9.3mm drill bit (187000Q) is now inserted into the main sleeve and drilled to its stop (a). Care should be taken to ensure that the direction of drilling follows the path taken by the Main Guide. If necessary, this may require the introducer to be raised or lowered slightly. Ideally, drilling with the 7mm and 9.3mm drill bits should be performed under lateral image intensification.



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This will enable any corrections needed to centralize the drill to be made during the procedure.

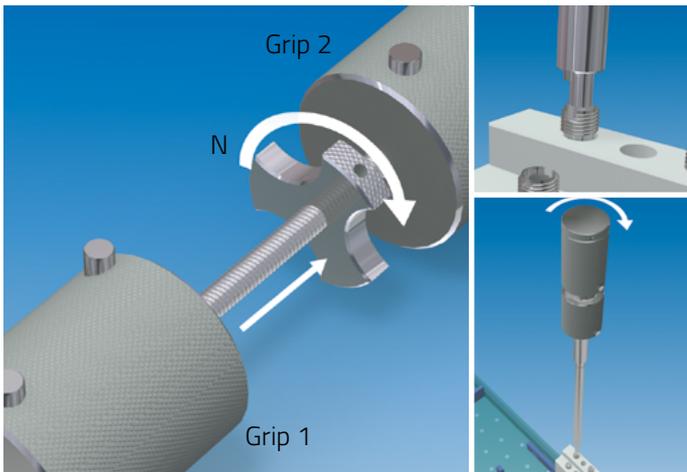


The correct length neck screw is now attached to the Neck Screwdriver (184000). This instrument has:

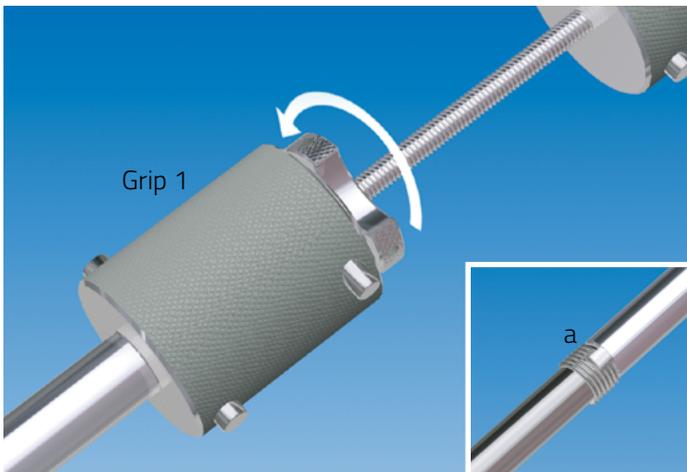
1. An inner shaft (a) activated by Grip 3. This has a threaded end, which engages the neck screw head.
2. An outer shaft (b) activated by Grip 1, which screws the outer barrel of the neck screw to the plate.
3. A middle shaft (c) activated by Grip 2. This shaft has a hexagonal end for screwing the neck screw into the bone.
4. A Nut, for compression of the fracture.
5. Two Buttons D and E to release and separate the handle for cleaning.



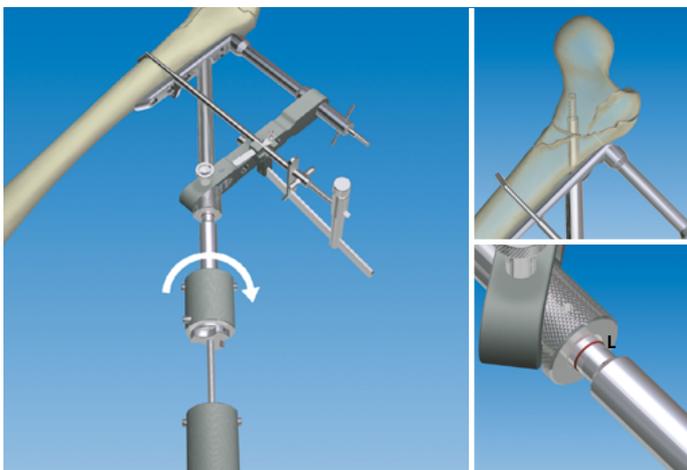
**PRECAUTION:** It is very important that the full set of instruments and full range of femoral neck screws are available.



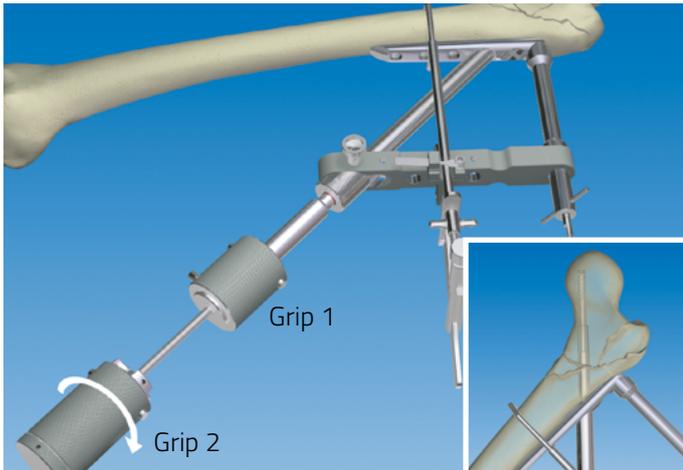
If the neck screws are correctly loaded in their dispenser, the hexagonal recess in each will be at the level of the head of the screw barrel, ready for attachment to the Screwdriver. The nut "N" on the Screwdriver is turned until it is touching grip 2. This ensures that the hexagonal end of the Screwdriver is extended to its limit. The Screwdriver is now held vertically and its hexagonal end engaged in the hexagonal recess of the screw. Grip 3 is now pushed down and turned clockwise, applying gentle pressure while turning, to engage the threaded recess in the screw head.



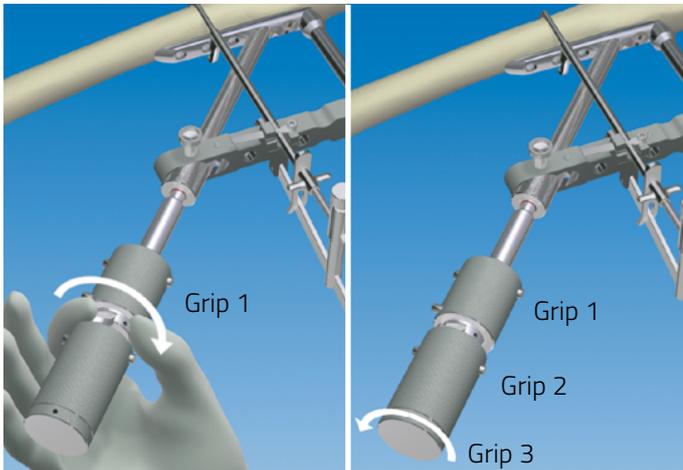
Grip 1 is now slid forward until the teeth of the Screwdriver are seated in the cutouts (a) of the screw barrel thread. The teeth are locked in position by turning the nut "N" down to grip 1, keeping them aligned with the cutouts while doing so. Care should be taken not to overtighten as this may disturb the alignment.



The selected neck screw, mounted on the Screwdriver, is introduced into the main sleeve. Grip 1 is turned until the thread at the base of the screw barrel is completely screwed into the plate. When the line marked "L" on the Screwdriver shaft reaches the head of the main sleeve, this indicates that the threads of the screw barrel are entering the plate.



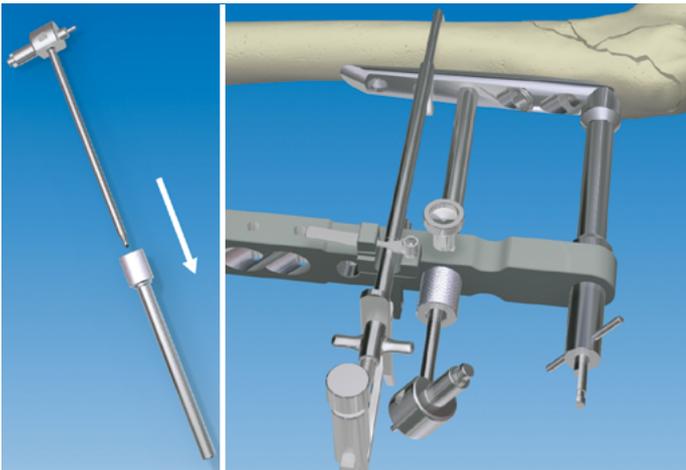
To advance the shaft of the screw into the femoral neck and head, nut "N" is turned counterclockwise until it meets grip 2. Under image intensification, grip 2 is now turned until the neck screw is positioned in the subchondral bone of the femoral head.



To exert a backward force on the screw to compress the fracture, nut "N" is now turned clockwise until it reaches grip 1. Further turning of nut "N" will compress the fracture. This should be done with the shaft trocar or, preferable with two fingers, under image intensification to ensure that the screw threads remain in place and do not tear the fragile trabeculae of the femoral head during the procedure. The neck screw can now be disengaged from the Screwdriver by turning grip 3 counterclockwise until an audible click is heard.

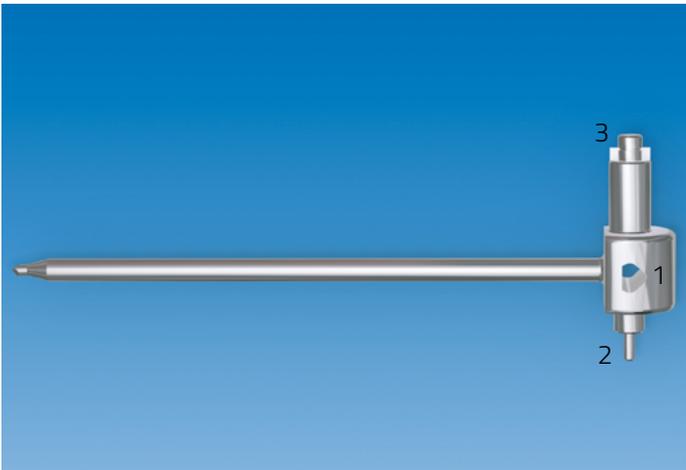


The impactor (200000) is now introduced through the main sleeve until it engages the barrel of the neck screw (a slight click is audible). A light hammer is used to minimally deform the thread in the plate. This will prevent the possibility of any backing out of the neck screw barrel during the cyclic loading produced on walking. The main sleeve and impactor are now removed.



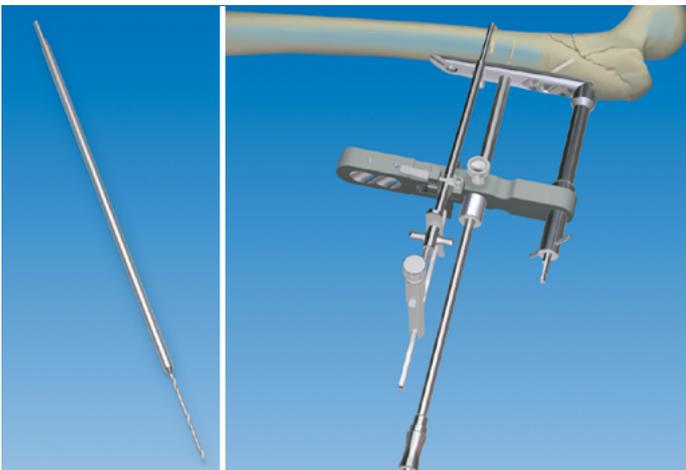
The shaft sleeve (203000) and shaft trocar (204000Q) are now inserted through either the proximal or distal vertical hole of the introducer using the small skin retractor to assist entry into the incision.

The shaft sleeve is locked into position with a bolt (194000) inserted through the introducer, and the shaft trocar withdrawn.

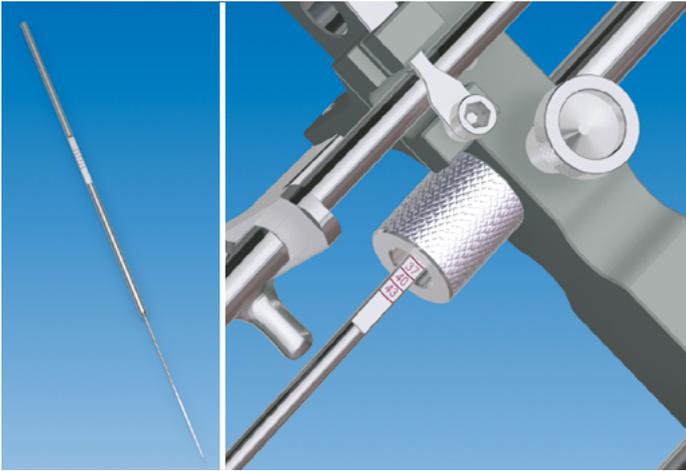


Note that the shaft trocar has three additional functions:

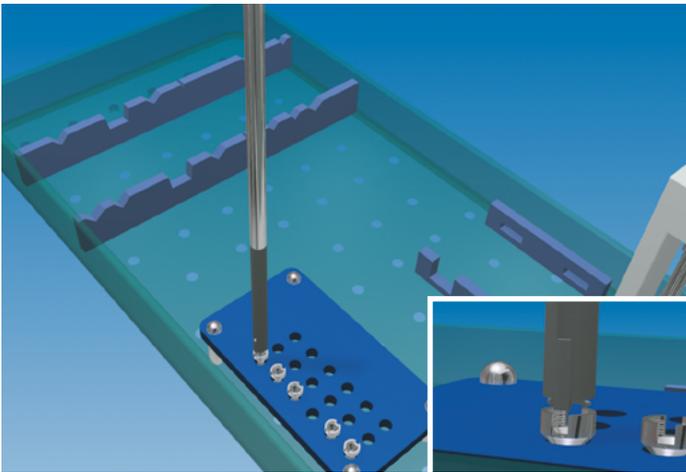
1. A triangular hole for attachment to the shaft Screwdriver if manual application of the shaft screws is desired.
2. A cylindrical protrusion to assist in turning the grips of the neck Screwdriver.
3. A short Screwdriver for the neck screw barrel.



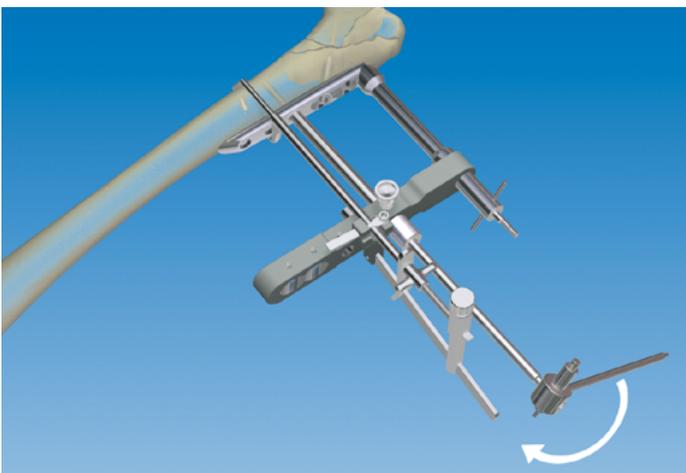
The 3.2mm step drill bit is now used to predrill the bone.



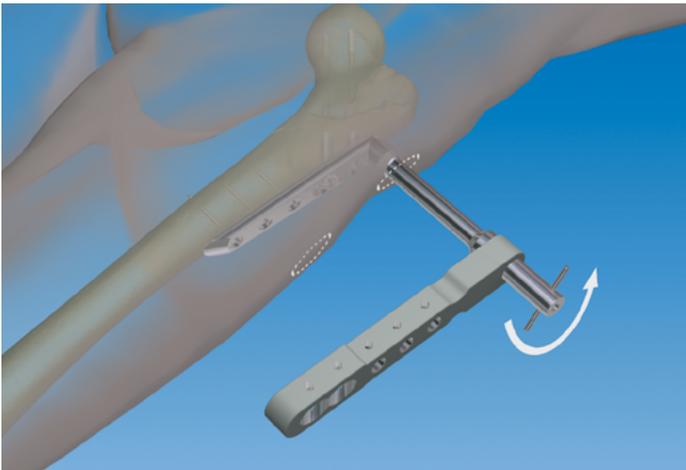
The depth gauge (205000) is used to measure the length of bone screw required. It is introduced through the predrilled track and withdrawn until its hook engages the outer medial surface of the femur. The number that is now adjacent to the edge of the shaft sleeve head corresponds to the length of shaft screw required.



The correct length shaft screw is now attached to the shaft Screwdriver (185000Q) using gentle pressure. Note that the end of this Screwdriver is spring-loaded to grip the screw firmly for insertion or removal.



A power tool is normally used for insertion of the shaft screws. In this case insertion should be performed in stages, while listening carefully to the sound of the instrument to avoid stripping the thread in the bone. Where manual insertion is preferred, the triangular recess in the head of the shaft trocar is fitted over the end of the shaft Screwdriver. In osteoporotic bone it is recommended that the shaft screws are inserted manually.

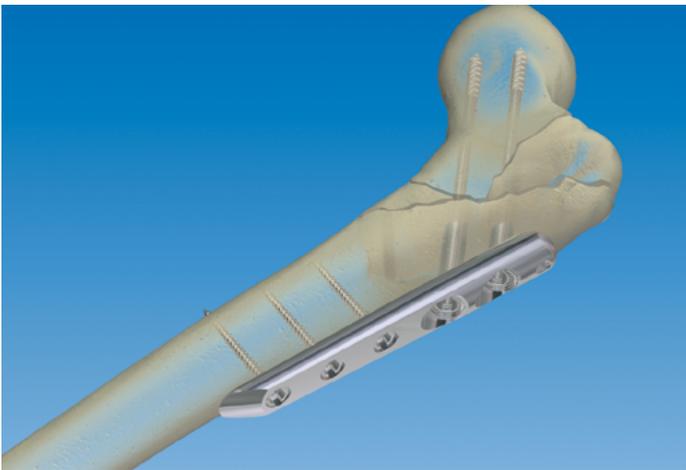


The bone hook is now removed by simply reversing the steps used for its insertion. The butterfly pin must now be removed. The remaining two shaft screws are now inserted as described above, followed by the second (proximal) neck screw. This neck screw is also inserted using the Main Guide in order to measure the length of screw required. Following screw introduction, the barrel is impacted to minimally deform the thread in the plate as before.

The introducer is now unlocked (butterfly screw) and removed.



**PRECAUTION:** For a successful result after insertion of a P.C.C.P, the patient should be mobilised immediately, weightbearing as much as can be tolerated. Full weightbearing is encouraged from the beginning.



## FRAME REMOVAL

Part #	Description
184000	NECK SCREWDRIVER
204000Q	SHAFT TROCAR
185000Q	SHAFT SCREWDRIVER

To remove the neck screws, the neck screwdriver is connected to the end of the screws (following procedure already described) and used to extract the screws. To remove the shaft screws, a power tool is normally used in "reverse" mode. Where manual removal is preferred, fit the triangular recess of the end of the shaft trocar over the end of the shaft screwdriver. Remove the shaft screws with a counter-clockwise movement.

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](mailto: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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