

IRENE[®]



Indication

- ◎ - Petrochanteric fractures (31-A1 31-A2)
- ◎ Intertrochanteric fractures (31-A3)
- ◎ High subtrochanteric fractures
- ◎ Especially suitable for the patients with osteoporosis

PFNA

Proximal Femoral Nail-Antirotation

Naton Medical Group
Tianjin ZhengTian Medical Instrument Co., Ltd.

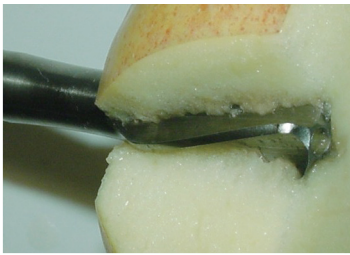
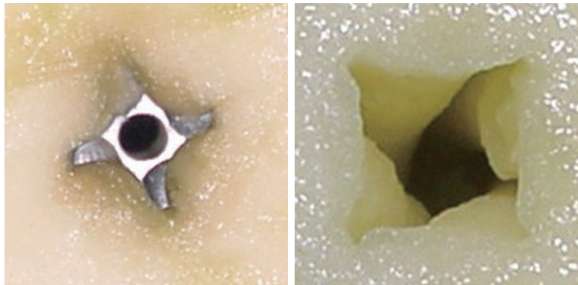
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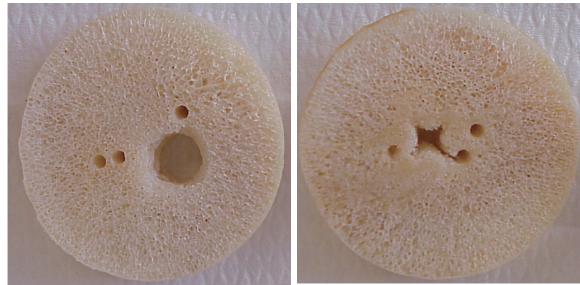


PFNA Blade

Anti-rotation and angular stability are successfully achieved by one component

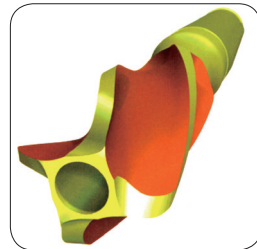


PFNA blade causes compression of the Cancellous bone while inserting, so as to raise the anchor force. This makes the blade more suitable for the patients with Osteoporosis.



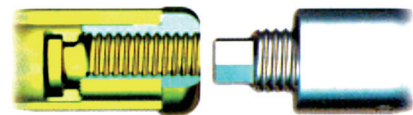
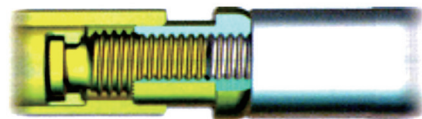
PFNA Blade causes less destruction of bone comparing with other implants.

The increased stability caused by bone compaction around the PFNA blade has been biomechanically proven to retard rotation and varus collapse. Such biomechanical tests demonstrated that the PFNA blade had a significantly higher cut-off resistance compared to commonly-used screw systems.



Outer Locking—Inserting PFNA Blade with

All the inserting procedures of PFNA Blade are outer operated
PFNA Blade can lock automatically so as to prevent the blade and femoral head from rotating.

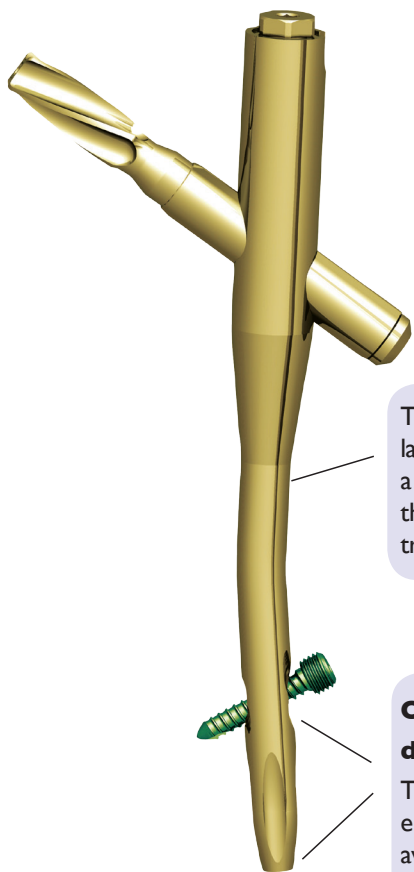


PFNA Blade unlocking status/ locking status.

PFNA NAIL

Perfect match

Anatomical design ensures perfect match with femur. PFNA nail designs accordingly to the Clinical validation of some famous manufacturers like AO.



The PFNA has medial-lateral angle of 5°, This allows insertion at the tip of the greater trochanter.

Optimal stress distribution.

The flexible PFNA tip eases insertion and avoids stress on the bone at the tip of the PFNA.

Indications

- Petrochanteric fractures (31-A1 31-A2)
- Intertrochanteric fractures (31-A3)
- High subtrochanteric fractures
- Especially suitable for the patients with osteoporosis



SPECIFICATIONS

The PFNA is available in 2 sizes with 4 kinds of diameters

- PFNA , length 180mm and 200mm
- PFNA , diameter 9mm, 10mm, 11mm and 12mm

The PFNA blade is available from 80mm to 120mm (every 5mm an increment) with a diameter of 10.5mm

Femoral neck shaft angle

130°

Locking screw: diameter: 4.8mm

Length: 25mm-85mm (every 5mm an increment)

PFNA



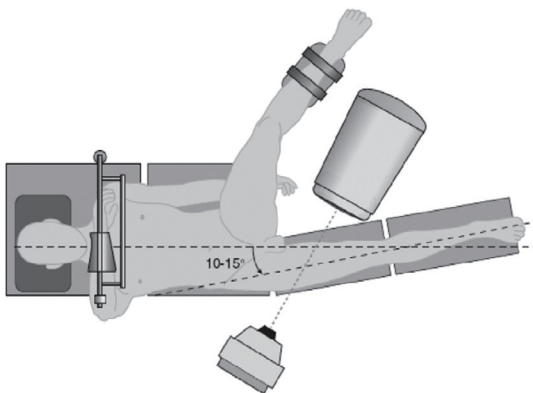
distal static locking status

distal static locking status

1

Patient position

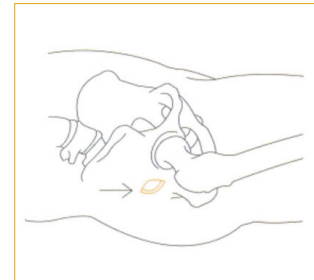
Position the patient supine on an extension table or a radiolucent operating table. Abduct the unaffected leg as far as possible and place it on a leg support, so that it does not allow free fluoroscopic examinations. For an unimpeded access to the medullary cavity, abduct the upper body by about 10–15° to the unaffected side (or adduct the affected leg by 10–15°).



2

Fracture reduction

Perform closed reduction of the fracture under image intensifier control. Carry out open reduction, if the result is not satisfactory.



Note: Exact anatomical reduction and secure fixation of the patient to the operating table are essential for easy handling and a good surgical result.

3

Surgical approach

Palpate the trochanter major

Make a 5 cm incision approximately 5 to 10 cm proximal from the tip of the greater trochanter. Make a parallel incision of the fasciae of the gluteus medius and split the gluteus medius in line with the fibres.

When using the Insertion Handle for PFNA Nail, extend the incision distally.

1

Determination of PFNA entry point and guide wire insertion

In AP view, the PFNA entry point is usually on the tip or slightly lateral to the tip of the greater trochanter in the 5° curved extension of the medullary cavity, as the medial-lateral angle of the PFNA is 5°. This means that the 3.0 mm Guide Wire must be inserted on the tip or slightly laterally of the greater trochanter at an angle of 5° to the intended extension of the medullary.

Inserting guide wire

Position both 20.0/17.0 mm Protection Sleeve and 17.0/3.0 mm Drill Sleeve at the insertion point. Insert the guide wire through the protection sleeve and the drill sleeve. Then remove the drill sleeve.

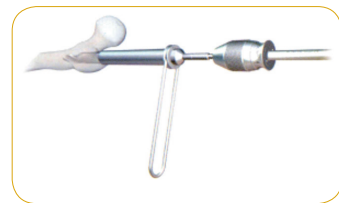


Note: The correct entry point and angle are essential for a successful result.

2

Opening of the femur

Guide the cannulated 17.0 mm Drill Bit through the 20.0/17.0 mm Protection Sleeve over the 3.0mm Guide Wire and drill with the Universal Chuck with T-handle as far as the stop on the protection sleeve. Remove the protection sleeve and the guide wire.



Note: It is recommended to open the femur by power tool at high speed or carefully by hand. To prevent dislocating the fracture fragments, avoid lateral movements or excessive compression forces.

3

Assembly of PFNA instruments with PFNA

Guide the Connecting Screw through the Insertion Handle and secure the PFNA to the insertion handle using the Hexagonal Wrench with T-handle. The diameter of the PFNA has already been determined during surgical preparation.



Note: Ensure that the connection between PFNA and insertion handle is tight (retighten, if necessary) to avoid deviations when inserting the PFNA blade through the insertion handle. Do not attach the aiming arm yet.

4

Use image intensifier control to insert the PFNA.

Carefully insert the PFNA manually as far as possible into the femoral opening.



Slight twisting hand movements help insertion. If the PFNA cannot be inserted, select a smaller size PFNA diameter or ream the medullary cavity to a diameter that is at least 1mm larger than that of the selected nail.

If necessary, light blows with the Hammer on the protection shield of the insertion handle can support the insertion of the PFNA.

The correct PFNA insertion depth is reached, as soon as the projected PFNA blade is positioned in the lower half of the femoral neck. A too cranial or too caudal PFNA position should be avoided as it can lead to malposition of the PFNA blade.

The anteversion can be determined by inserting a guide wire ventral to the femoral neck in the femoral head. In the medio-lateral view, place the insertion guide parallel to the guide wire to align the correct rotation of the PFNA.

Remove all guide wires. Do not reuse, but dispose of the guide wires.

Note:

- Always ensure that the PFNA is firmly attached to the insertion handle.
- Use only light blows on the protection shield of the insertion handle. Avoid unnecessary use of force to prevent loss of reduction or an iatrogenic fracture.

5

Preparation of guide wire insertion

Mount the appropriate 130° Aiming Arm and fix it firmly to the insertion handle.

Firmly secure the golden 16.0/11.0 mm Buttress Nut to the Protection Sleeve for PFNA Blade. For the insertion, insert the buttress nut through the aiming arm as far as the marking I.

Insert the golden 11.0/3.0 mm Drill Sleeve and the golden 3.0 mm Trocar through the protection sleeve.



6

Guide wire insertion

Advance the entire sleeve assembly for PFNA blade through the aiming arm to the skin. See marking on the 130° Aiming Arm. Make a stab incision in the area of the trocar tip. Advance the sleeve assembly through the soft tissues in direction of the lateral cortex until it clicks into the aiming arm.

Note: Ensure that the sleeve assembly clicks into the aiming arm. Otherwise it does not guarantee the exact position of the PFNA blade



Insert the sleeve assembly as far as the lateral cortex. Advance the Protection Sleeve to the lateral cortex using slight clockwise turns of the Buttress Nut. Prepare the passage of the protection sleeve by turning the internal golden 11.0/3.0 mm Drill Sleeve.

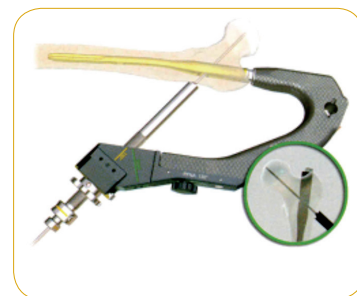
Note: The sleeve assembly must be in contact with the bone during the entire blade implantation. Do not tighten the buttress nut too firmly as this could impair the precision of the insertion handle and sleeve assembly.



Remove the trocar. Insert a new 3.0 mm Guide Wire through the golden 11.0/3.0 mm Drill Sleeve into the bone. Verify both direction and position under image intensifier in AP and lateral view. In the AP view, the position of the guide wire should be in the lower half of the femoral neck. In lateral view, the wire should be positioned in the centre of the femoral neck. Insert the guide wire subchondrally into the femoral head, but at a distance of least 5mm from the joint.

Note: If the PFNA or the guide wire has to be repositioned, remove the guide wire, release the sleeve assembly with buttress nut from the aiming arm by pressing the button on the clamp device and remove it. The PFNA can be repositioned only by rotation, deeper insertion or partial retraction.

Reinsert the sleeve assembly and turn the buttress nut clockwise to position the assembly on the bone. Reinsert the guide wire.

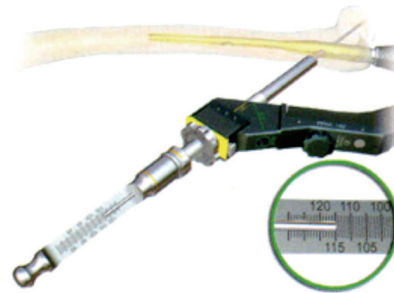


7

Measuring of PFNA blade length

Verify the position of the guide wire in AP and lateral view before measuring the length.

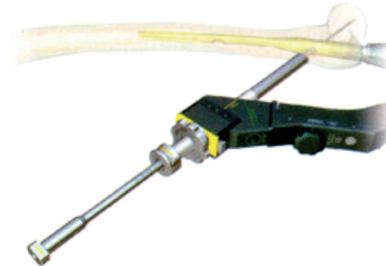
Guide the Measuring Device for 3.0 mm Guide Wire over the guide wire, advance it to the protection sleeve and determine the length of the required blade. The measuring device indicates the exact length of the guide wire in the bone ensuring that the position of the PFNA blade will be flush with the tip of the guide wire. The correct position of the PFNA blade is approximately 5–10 mm below the joint level. If the guide wire's position is subchondral, subtract 5–10 mm, as in the DHS system, to position the PFNA blade correctly.



8

Removal of drill sleeve

Carefully remove the golden 11.0/3.0 mm Drill Sleeve without changing the position of the guide wire.

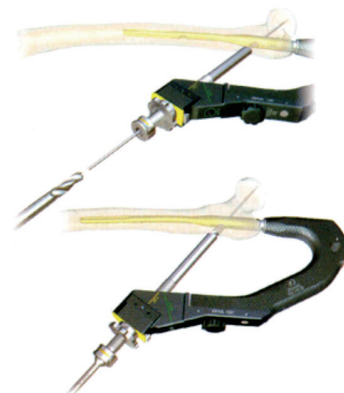


9

Opening of lateral cortex for PFNA blade insertion

Push the cannulated 11.0 mm Drill Bit over the 3.0 mm Guide Wire. Drill to the stop. This opens the lateral cortex

Note: if the guide wire has been bent slightly during insertion, guide the drill bit over it using carefully forward and backward movements. However, if the wire has been bent to a greater extent, reinsert it or replace it by a new guide wire. Otherwise, the tip of the drill bit risks to break off



10 Drill hole for PFNA blade

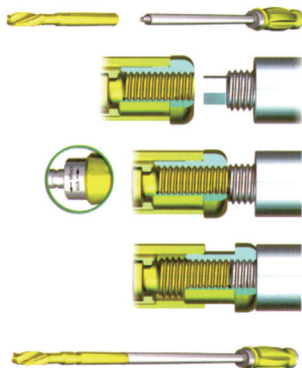
Set the measured length of the blade on the cannulated 11.0 mm Reamer by fixing the Fixation Sleeve in the corresponding position. Read off the correct length on the side of the fixation sleeve pointing towards the tip of the drill bit.

Push the reamer over the 3.0 mm Guide Wire. Drill to the stop. The fixed fixation sleeve prevents further drilling. Use the reamer only after drilling the lateral cortex with the drill bit.

11

Assembly of PFNA blade and PFNA inserter

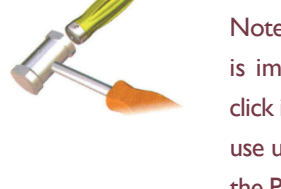
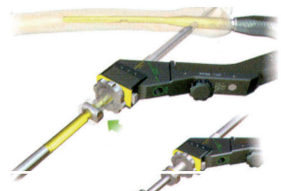
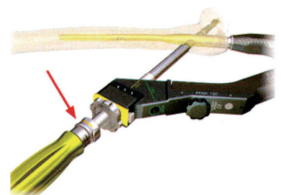
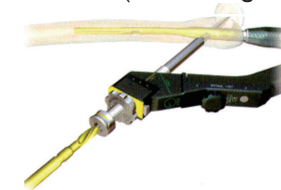
The PFNA blade is supplied in a locked state. Use slight anti-clockwise pressure to insert the Inserter into the selected PFNA blade to the stop. Ensure its firm fit. This procedure unlocks the PFNA blade. Now the blade rotates freely. This is essential for the implantation of the PFNA blade.



12

Insertion of PFNA blade

Insert both blade and Inserter over the 3.0mm Guide Wire through the protection sleeve. In view of the particular shape of the PFNA blade, align it with the protection sleeve for insertion (see marking on the protection sleeve), pressing



at the same time the button on the protection sleeve. Hold the golden handle of the inserter and manually insert the blade over the guide wire as far as possible into the femoral head. Insert the PFNA blade to the stop by hammering lightly with the Hammer /

Use image intensification to check the position of the PFNA blade.

Note: Inserting the blade to the stop is important, as the inserter has to click into the protection sleeve. Do not use unnecessary force when inserting the PFNA blade.

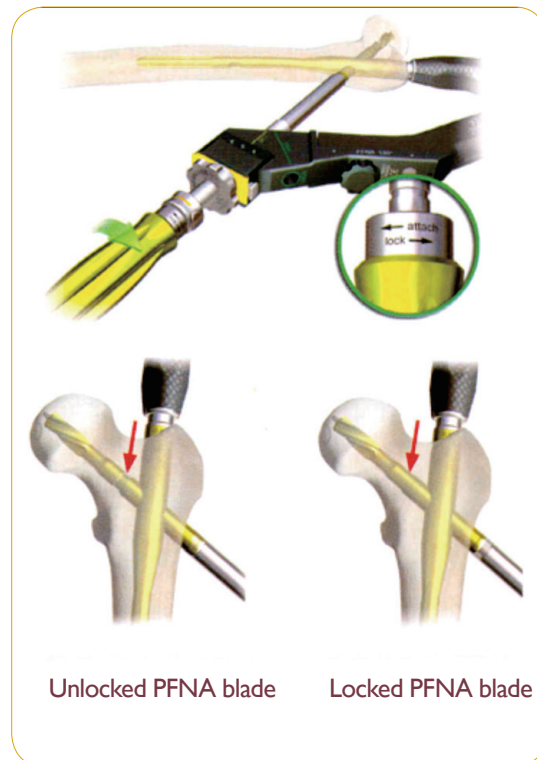
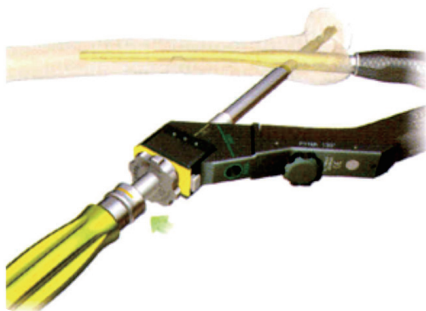
13

Locking of PFNA blade

Turn the inserter clockwise to the stop. The PFNA blade is now locked. Verify PFNA blade locking intraoperatively. The PFNA blade is locked if all gaps are closed. If the PFNA blade cannot be locked, remove it and replace it by a new PFNA blade.

Note: Gliding of the PFNA blade is guaranteed.

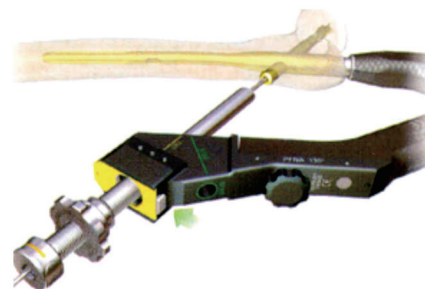
Press the button on the protection sleeve to remove the inserter. Remove and dispose of the guide wire.



14

Removal of protection sleeve

Release and remove the protection sleeve and the buttress nut by pressing the button on the clamp device of the aiming arm.



15

Static distal locking

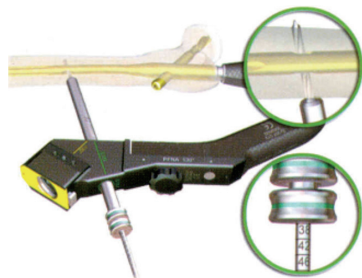
Remove the green Trocar and use the 4.0 mm Drill Bit to drill through both cortices. The tip of the drill bit should protrude by 2 to 4 mm, and the protection sleeve should be in direct contact with the bone. Read the length of the required locking bolt directly off the marking on the drill bit.

Note:

- Always make sure that no diastasis has occurred intraoperatively before beginning distal locking. Diastasis can cause delayed healing.
- Always ensure that the connection between PFNA, insertion handle and aiming arm is good, otherwise reaming for the distal locking bolt can damage the PFNA.

Alternative length measuring:

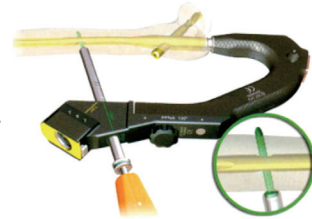
Determine the length of the bolt with the Depth Gauge for Locking Bolts. Advance the depth gauge to the cortex. Then draw back the hook until it engages in the opposite cortex. Add 2 to 4 mm to the measured length to ensure good engagement of the locking bolt in the opposite cortex.



16

Insertion of locking screw

Insert the locking bolt through the protection sleeve using the large Hexagonal Screwdriver.



17

Removal of instruments

Remove the protection sleeve and the aiming arm. Use the hexagonal socket to loosen the connecting screw and remove the insertion handle.

18

Insertion of end cap

Use the end cap with 0 mm extension if the nail end is flush with the upper edge of the trochanter major.

Guide the cannulated end cap to the proximal end of the nail. Fully insert the end cap into the nail. The last turns of the end cap in

the nail will offer increased resistance. Continue to turn until the stop of the end cap touches the proximal nail end. This prevents the end cap from slipping out. Remove the hexagonal screwdriver shaft, the ratchet wrench and the guide wire.



Implant removal

1 Removal of PFNA blade

After an incision through the old scars, locate the PFNA blade by palpation or under image intensification. Insert the 3.2 mm Guide Wire. Push the Extraction Screw over the guide wire and use gentle pressure to turn it anticlockwise into the PFNA blade. Use light hammer blows with the Slotted Hammer to remove and dispose of the PFNA blade.



2 Removal of PFNA end cap, PFNA, and locking bolt

First remove the PFNA End Cap. Insert the hook of the Guide Wire with Hook through the end cap. Then guide the 4/11 mm Hexagonal Screwdriver Shaft over the guide wire to the end cap. As soon as this connection is established, remove the end cap using the 11 mm Ratchet Wrench. Remove the PFNA. Attach the Guide Rod for PFNA to the PFNA nail, and only then use the Hexagonal Screwdriver to remove the distal locking bolt. Mount the large Holding Sleeve onto the hexagonal screwdriver to facilitate removal of the locking bolt.



Note: Remove the locking bolt only after attaching the guide rod to the PFNA. This prevents the PFNA from rotating in the bone. Attach the Slotted Hammer to the guide rod to remove the PFNA. Ensure that the guide rod fits firmly into the PFNA. Tighten with the 4.5 mm Pin Wrench. Use gentle hammer blows to extract the PFNA from the femur.

Insertion depth of the PFNA blade

Correct the insertion depth of the PFNA blade

Remove the inserter, the sleeve assembly and the aiming arm. Use gentle anticlockwise pressure to insert the Extraction Screw over the guide wire into the PFNA blade. Advance the now unlocked PFNA blade to the desired insertion depth by applying gentle blows with the Slotted Hammer. Turning it clockwise to the stop allows relocking of the PFNA blade.



Cleaning

Intra- and postoperative cleaning

Using cleaning stylet to clean.



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