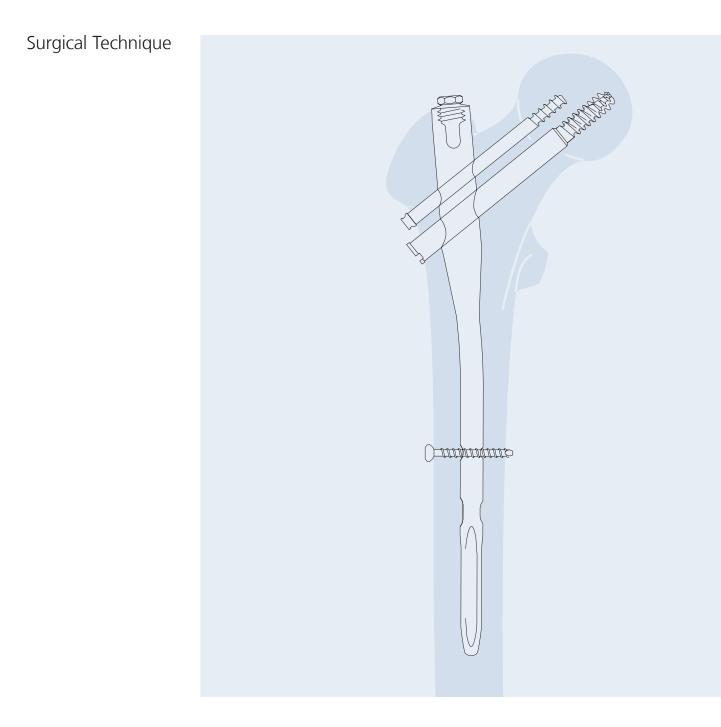
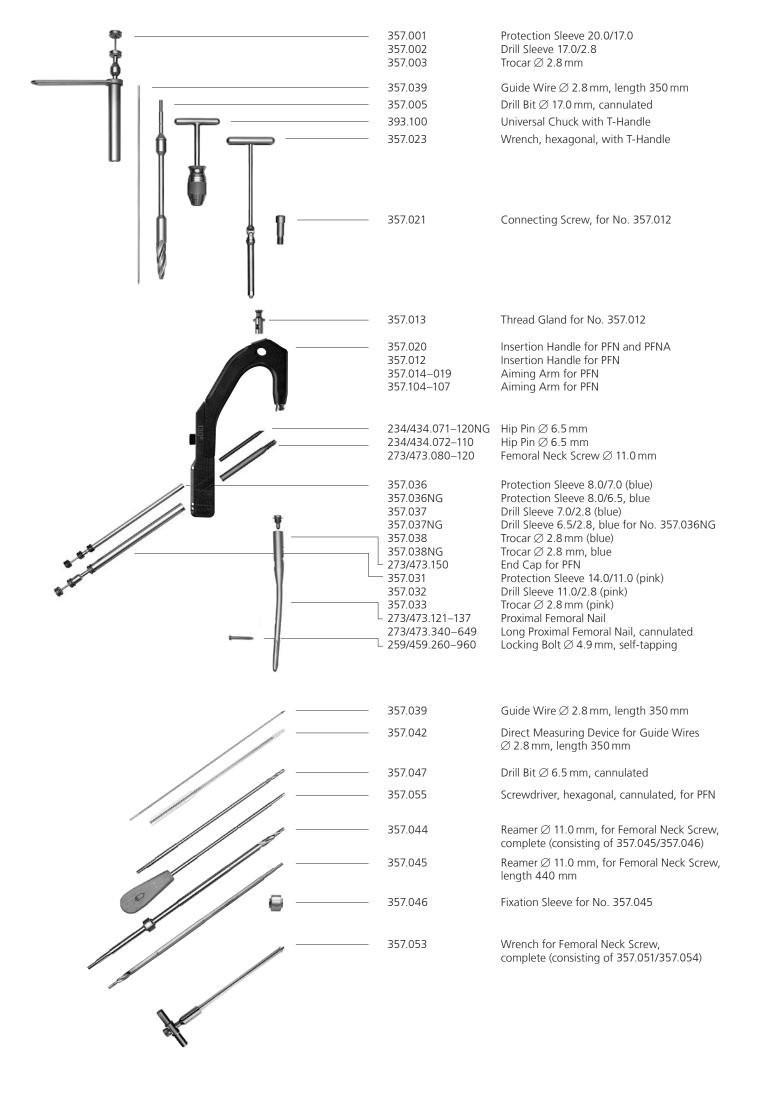
PFN. Proximal Femoral Nail Standard/Short, PFN Long PFN



This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.





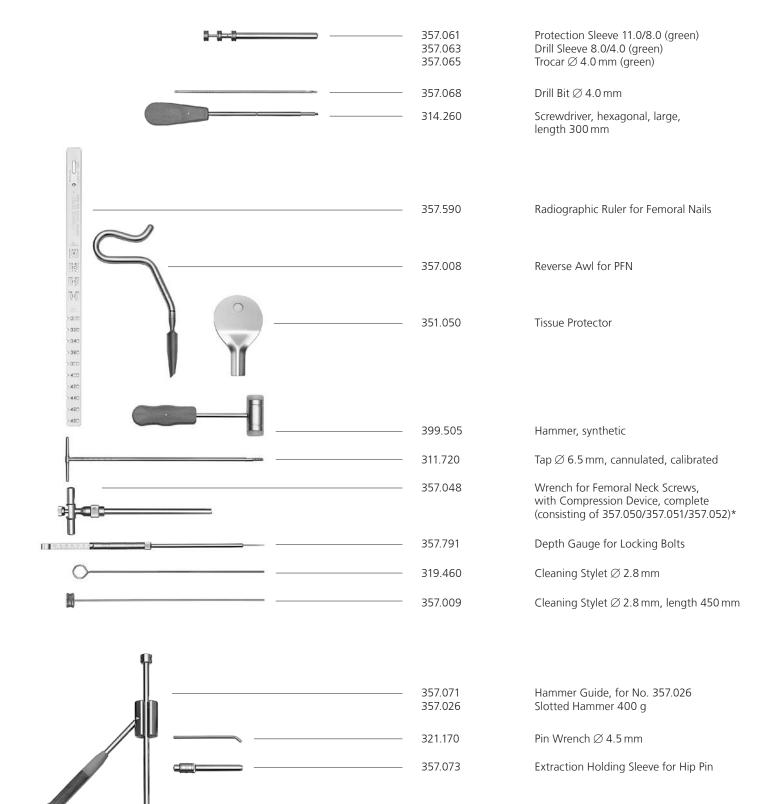


Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Table of contents

Implants for Standard/Short PFN	
•	3
Quick steps for Standard/Short PFN	4
Preparation for Standard/Short PFN	8
Surgical technique for Standard/Short PFN	10
Implants for Long PFN	24
Preparation for Long PFN	25
Surgical technique for Long PFN	26
Implant Removal	32
Cleaning of instruments	34
-	Preparation for Standard/Short PFN Surgical technique for Standard/Short PFN Implants for Long PFN Preparation for Long PFN Surgical technique for Long PFN Implant Removal

MRI Information

35

Standard/Short PFN

- The short femoral nail is used for small stature.

Indications

- Pertrochanteric fractures
- Intertrochanteric fractures
- High subtrochanteric fractures

Contraindications

- Low subtrochanteric fractures
- Femoral shaft fractures
- Isolated or combined medial femoral neck fractures

Long PFN

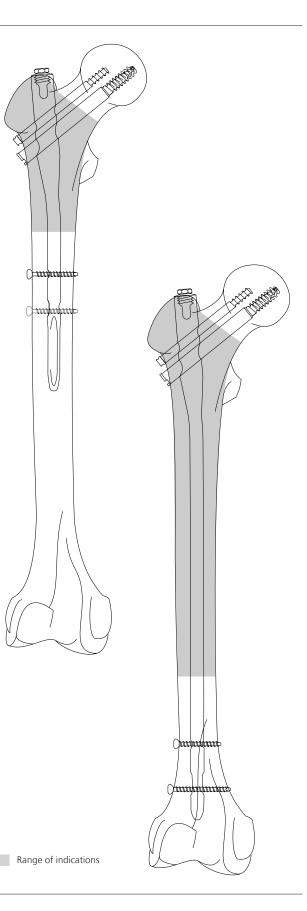
Indications

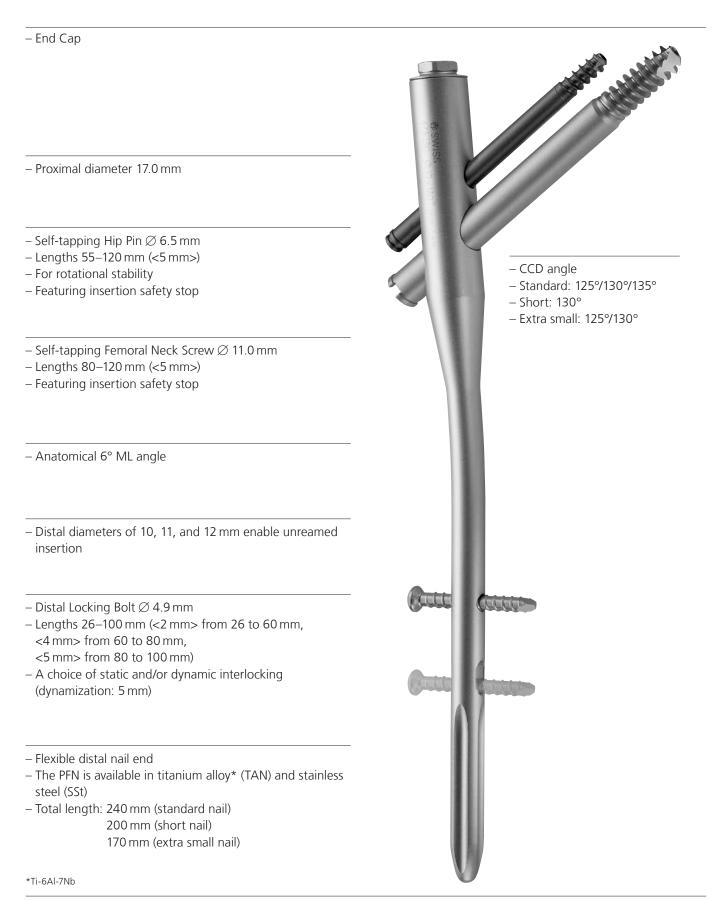
- Low and extended subtrochanteric fractures
- Ipsilateral trochanteric fractures
- Combination of fractures (trochanteric area/shaft)
- Pathological fractures

Contraindications

- Isolated or combined medial femoral neck fractures

Note: ASLS, the Angular Stable Locking System, is indicated in cases where increased stability is needed in fractures closer to the metaphyseal area or in poor quality bone. For more details regarding the intramedullary fixator principle, please consult the ASLS surgical technique (DSEM/TRM/0115/0284) and concept flyer (036.001.017).

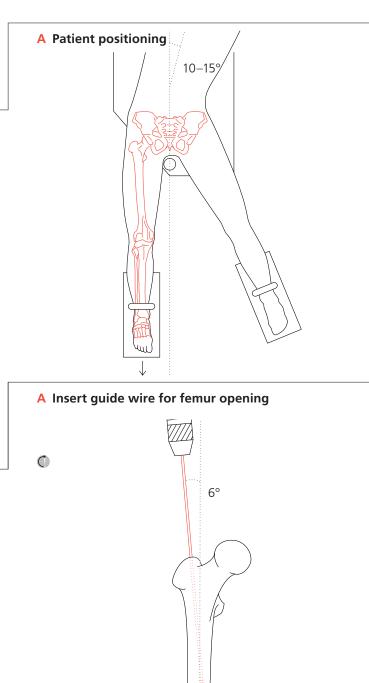


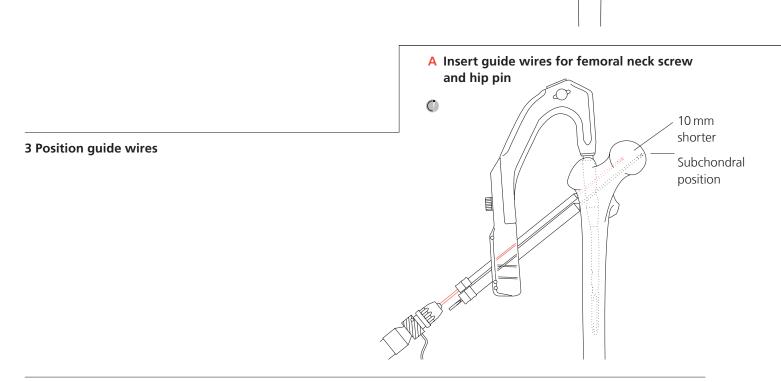


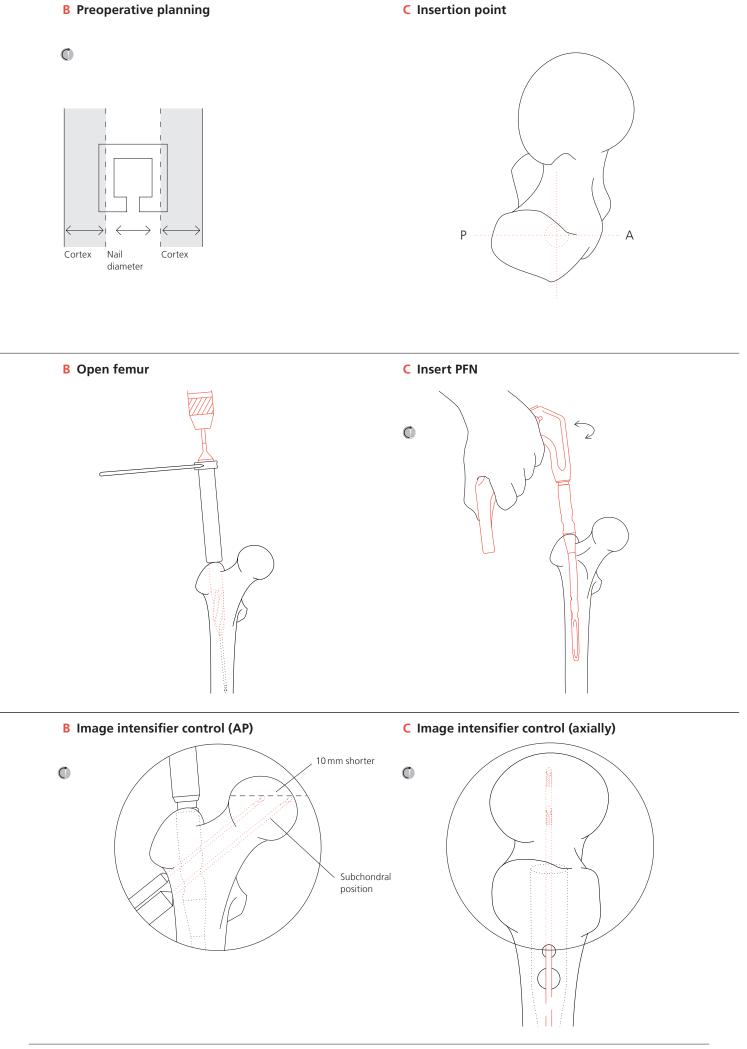


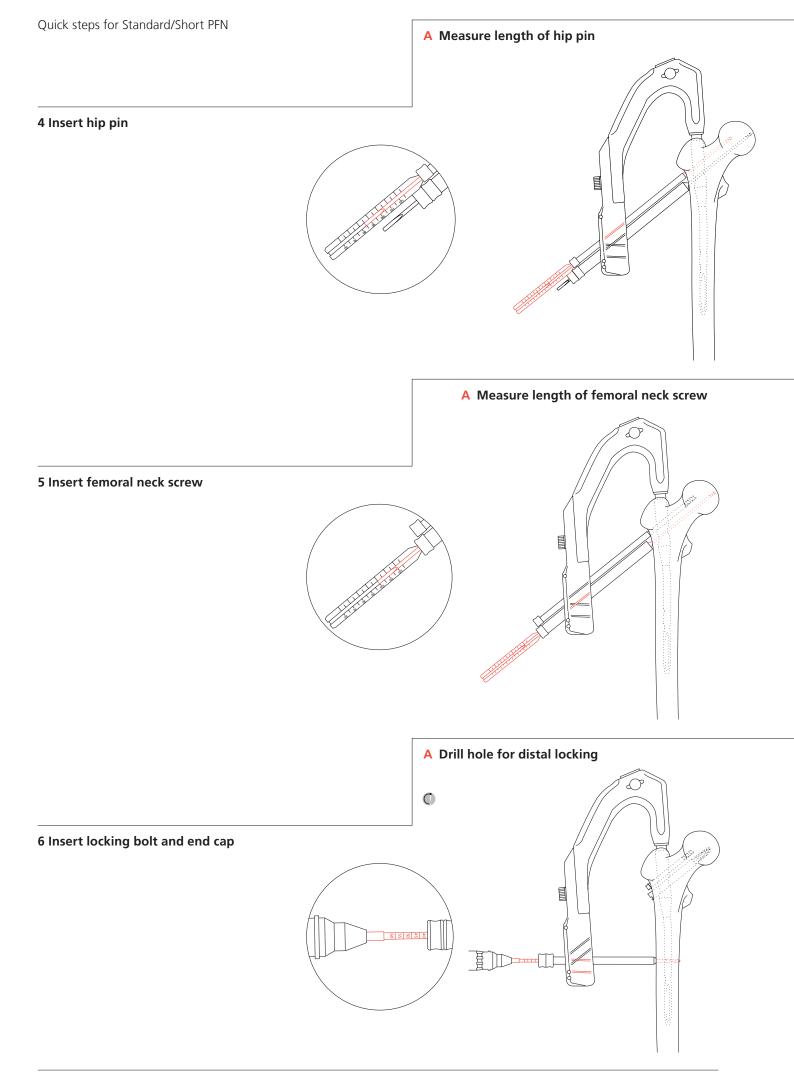
1 Preparation

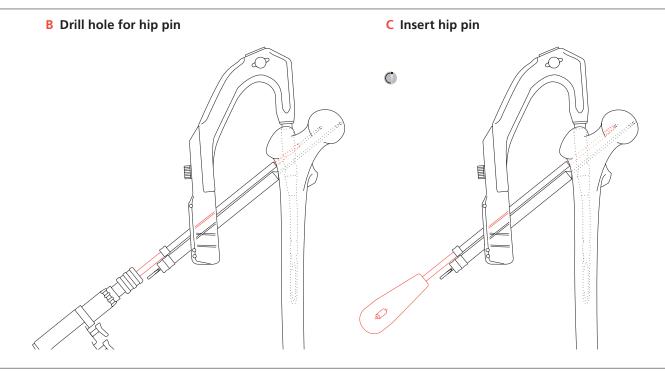
2 Insert PFN





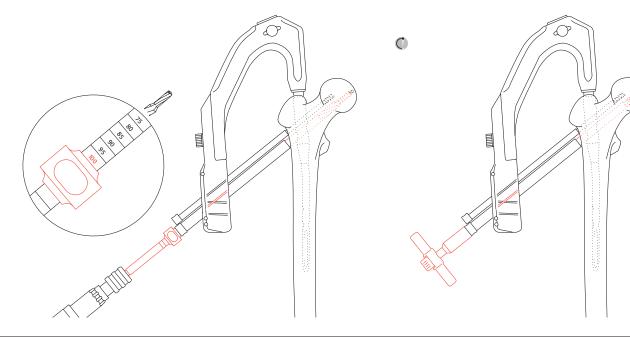




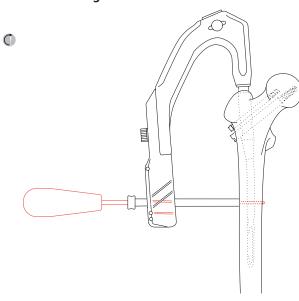


B Drill hole for femoral neck screw

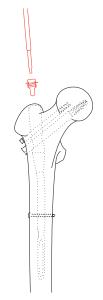
C Insert femoral neck screw



B Insert locking bolt



C Insert end cap



Position patient

Position patient supine on an extension table or a radiolucent operating table. Position the C-arm of the image intensifier in such a way that it can visualize the proximal femur exactly in the lateral and AP planes.

For unimpeded access to the medullary cavity, abduct the upper part of the body by about $10-15^{\circ}$ to the contralateral side (or adduct the affected leg by $10-15^{\circ}$).

Determine CCD angle

Take an AP X-ray of the unaffected side preoperatively. Determine the CCD angle using a goniometer or the preoperative planning template.

Standard PFN is available in 125°/130°/135°. Short PFN is available in 130°.

Reduce fracture

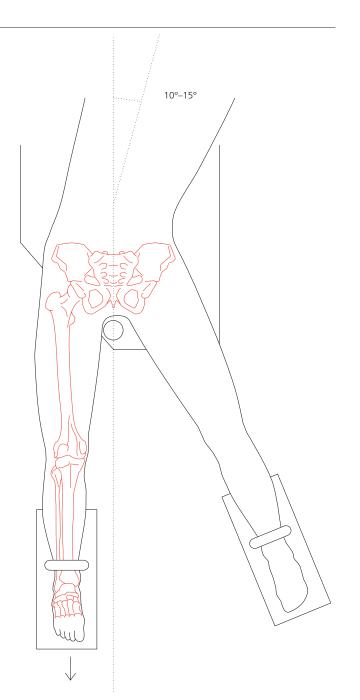
If possible carry out closed reduction of the fracture under

image intensifier control. If this procedure cannot be performed in a closed manner, then open reduction is required.

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

Precautions:

- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.



Determine nail diameter

Determine the distal nail diameter by placing the AO/ASIF planning template over the isthmus on an AP X-ray.

Alternative

Under image intensifier control, place the Radiographic Ruler (357.590) on the femur and position the square marking over the isthmus. If the transition to the cortex is still visible to the left and right of the marking, the corresponding nail diameter may be used.

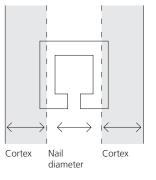
If the PFN \varnothing 10.0 mm is still too thick, the medullary canal must be reamed accordingly.

Note: When selecting the nail size, consider canal diameter, fracture pattern, patient anatomy and post-operative protocol.

Approach

Palpate the greater trochanter.

Make a 5 cm incision approximately 5 to 8 cm proximal from the tip of the greater trochanter. Make a parallel incision in the fasciae of the Gluteus medius and split the Gluteus medius in line with its fibres.



Determine nail insertion point and insert guide wire

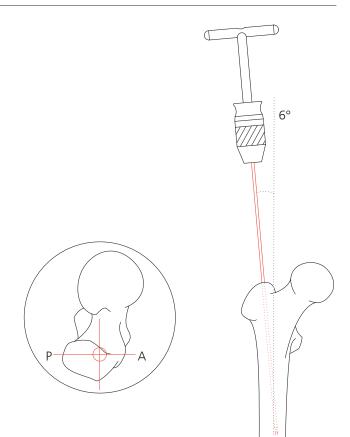
1

In the AP view, the nail insertion point is normally found on the tip or slightly lateral to the tip of the greater trochanter in the curved extension of the medullary cavity.

The mediolateral angle of the implant is 6°. This means that the 2.8 mm Guide Wire (357.039) must be inserted laterally at an angle of 6° to the shaft. On the lateral view, the guide wire must be located in the centre of the medullary canal, up to a depth of 15 cm. The guide wire can be inserted either manually with the Universal Chuck with T-Handle (393.100) or with a power tool with the Quick Coupling for Kirschner Wires.

Percutaneous technique: Insert guide wire through the Protection Sleeve 20.0/17.0 (357.001) and the Drill Sleeve 17.0/2.8 (357.002). Then remove the drill sleeve 17.0/2.8.

Note: A correctly selected insertion point and angle are essential for a good surgical result. Check the correct position
of the guide wire with the aid of x-rays and by positioning a nail anteriorly on the femur.



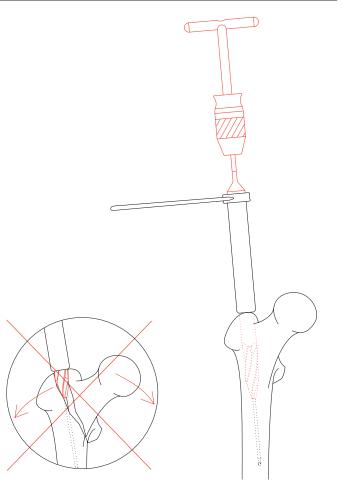
2 Open femur

Guide the 17.0 mm Cannulated Drill Bit (357.005) through the protection sleeve 20.0/17.0 over the guide wire and ream manually with the Universal Chuck with T-Handle (393.100) as far as the stop on the protection sleeve.

Remove protection sleeve and guide wire.

Precautions:

- Dispose of the guide wire, do not re-use.
- Particularly careful drilling is required with unstable multifragment fractures. Specifically, avoid varus displacement of the medial fragment by making sure that the hole is drilled both in the medial fragment and the lateral part of the femur.



Option: open with reverse awl

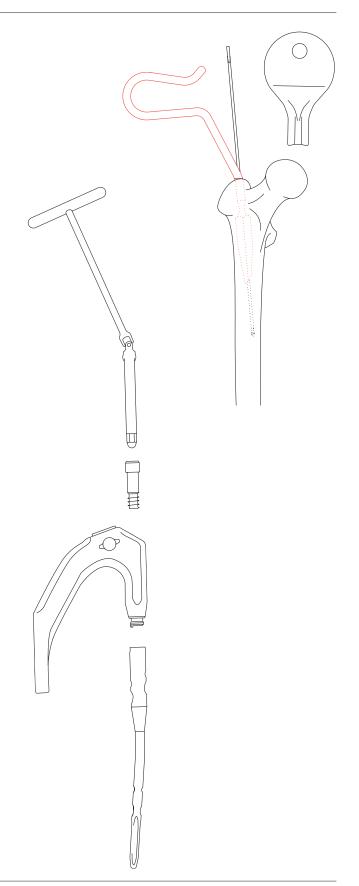
Open the femur or enlarge the entry point with the Reverse Awl (357.008). Use the Tissue Protector (351.050) to spare the soft tissues. Drive the awl over the guide wire into the femur until the marking on the awl chaft is level with the

the femur until the marking on the awl shaft is level with the trochanter tip.

3 Assemble instruments

Guide the Connecting Screw (357.021) through the Insertion Handle (357.012 or 357.020) and secure the nail tightly to the insertion handle using the Hexagonal Wrench (357.023). The nail diameter has already been determined during preparations for surgery.

Ensure that the connection is tight to avoid deviations when inserting the screws through the aiming arm. Do not attach the aiming arm yet.



Insert standard/short proximal femoral nail

Carefully insert the nail manually as far as possible into the femoral opening. Slight twisting hand movements help insertion. If the nail cannot be inserted, select a smaller size nail diameter.

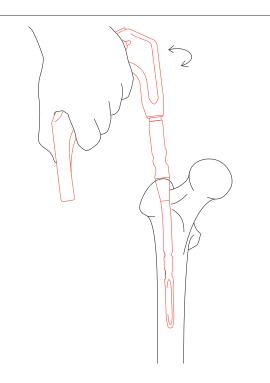
Insertion can be supported by light blows with the synthetic Hammer (399.505) on the mounted protection shield of the insertion handle.

The correct nail insertion depth is reached if the future position of the femoral neck screw is just above the calcar in the
distal half of the femoral neck. The future position of the femoral neck screw can be assessed on the AP view by means of the proximal holes in the nail. Ensure that sufficient space is also available for the hip pin.

Precautions:

4

- If the medullary canal is too narrow, it should be reamed to at least \oslash 10 mm.
- Make sure that the nail is tightly screwed to the insertion handle before inserting the nail.
- Tap gently on the insertion handle. The use of excessive force will result in loss of reduction or bone fracture. Apply taps only to the protection plate.
- An excessively cranial or caudal nail position will result in incorrect placement of the screws and should therefore be avoided at all costs.



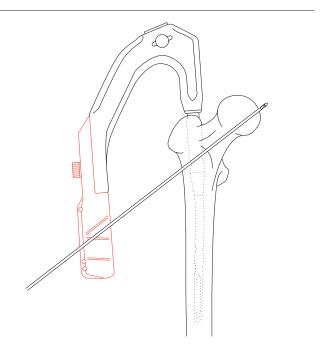
5 Prepare insertion of femoral neck screw and hip pin

For the insertion handle (357.012) secure the corresponding aiming arm (357.015 or 357.105/125°, 357.016 or 357.106/130°, 357.017 or 357.107/135° for standard PFN and 357.104/130° or 357.014/130° for short PFN and 357.119/130° for extra small PFN) tightly to the insertion handle.

Optional use the insertion handle (357.020) and secure the corresponding aiming arm (357.015/125°, 357.016/130°, 357.017/135° for standard PFN and 357.014/130° for short PFN and 357.119/130° for extra small PFN).

Select the screw and the colour-coded drill sleeve system consisting of protection sleeve, drill sleeve and trocar.

The position of the nail can now be checked on the AP view by positioning a guide wire over the aiming arm.



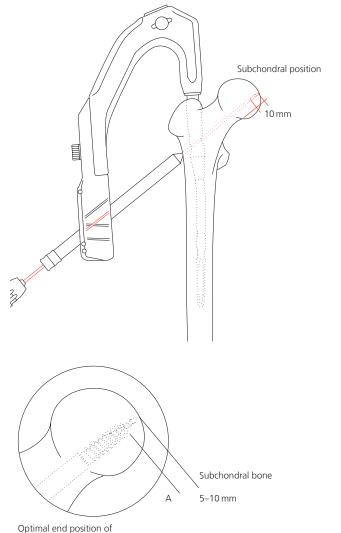
6 Insert guide wire for femoral neck screw

Make a stab incision and insert the pink Drill Sleeve System (357.031/357.032/357.033) through the aiming arm until the bone is reached. Mark the femur and remove the trocar.

Insert a new 2.8 mm Guide Wire (357.039) through the drill sleeve, check direction and position under the image intensifier in AP and lateral views. The correct position of the femoral neck screw tip (A) on the AP image is at a distance of 5 to 10 mm from the subchondral bone. The guide wire will therefore need to be inserted to the subchondral bone or up to a maximum distance of 5 mm away. In the lateral view the wire should be located in the centre of the femoral neck.

Note: If the guide wire is not in the desired position or if it is bent it must be reinserted. Remove the guide wire and the drill sleeve system. The nail must be repositioned by means of rotation, deeper insertion or slight retraction. Reset the drill sleeve system and introduce a new guide wire.

Precaution: Make sure the handle is not moved before inserting the hip pin guide wire. Drilling over a bent guide wire can result in drill breakage or damaging of the nail itself.



femoral neck screw

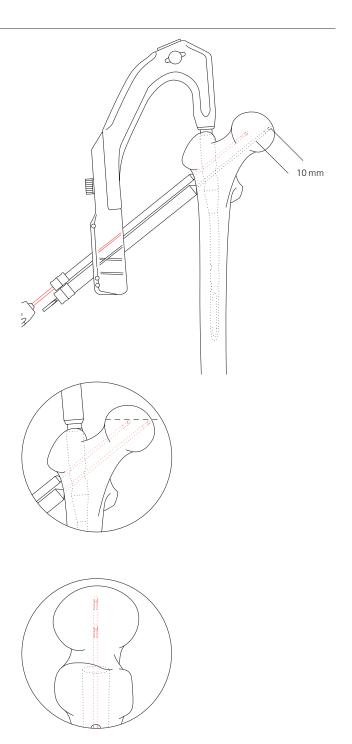
7 Insert guide wire for hip pin

Insert the blue Drill Sleeve System (357.036/357.037/357.038 or 357.036NG/357.037NG/357.038NG) through the blue drill hole on the aiming arm to the bone and mark the femur. Then remove the trocar and insert a second, new 2.8 mm guide wire through the drill sleeve into the bone. The insertion depth of the guide wire should be 10 mm less than the insertion depth of the femoral neck screw guide wire. This ensures that the hip pin will not take weight load but only fulfill the anti-rotary function.

Note: Verify that the guide wires are parallel in both planes and that their tips form a horizontal line on the AP view.

Precaution: The use of a hip pin is essential to avoid rotation.

Note: As only the femoral neck screw has a load-bearing function, the hip pin should always be 15–20 mm shorter than the femoral neck screw (as shown in the drawing).



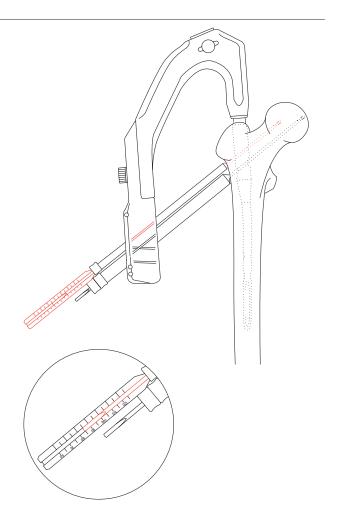
8 Remove drill sleeve

The blue drill sleeve (357.037 or 357.037NG) must be carefully removed without moving the guide wires from their original positions. Before the length measurement, recheck
the position of the guide wires on the AP view.

9 Measure length of hip pin

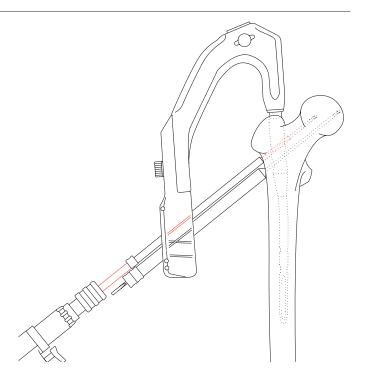
In order to prevent possible rotation of the medial fragment when inserting the femoral neck screw, prior insertion of the hip pin is recommended.

Guide the Direct Measuring Device (357.042) through the protection sleeve 8.0/7.0 or 8.0/6.5 (NG) to the bone and determine the required length of the hip pin. The length of this pin is indicated on the measuring device and is calculated to end 5 mm before the tip of the guide wire.



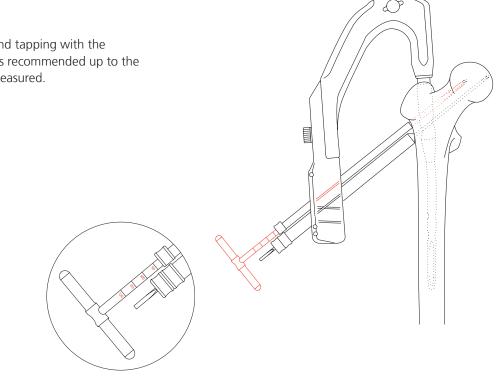
10 Drill hole for hip pin

Advance the 6.5 mm Cannulated Drill Bit (357.047) over the 2.8 mm guide wire. Drill completely to the stop (maximum reaming depth: 45 mm). As the tip of the hip pin is self-tapping, usually no further drilling and tapping is needed.



11 Procedure with hard bone

With hard bone, further drilling and tapping with the 6.5 mm Calibrated Tap (311.720) is recommended up to the length of the hip pin previously measured.



12 Insert hip pin

Using the Cannulated Hexagonal Screwdriver (357.055), (1) insert the selected hip pin over the guide wire completely to the stop.

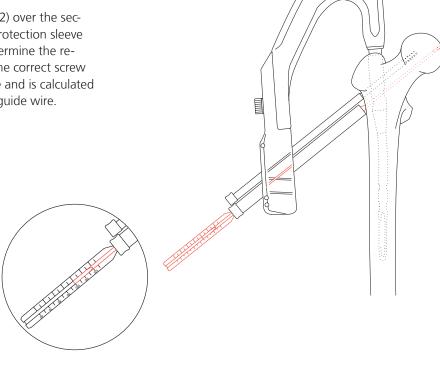
Remove and discard the 2.8 mm guide wire of the hip pin.

Precaution: Do not insert the hip pin with undue force. Ensure that the lateral end of the hip pin clearly protrudes from the lateral cortex and is not inserted into it.

13

Measure length of femoral neck screw

Guide the Direct Measuring Device (357.042) over the second 2.8 mm guide wire through the pink protection sleeve 14.0/11.0 until it touches the bone and determine the required length of the femoral neck screw. The correct screw length is indicated on the measuring device and is calculated to end approx. 5 mm before the tip of the guide wire.



D

14 Drill hole for femoral neck screw

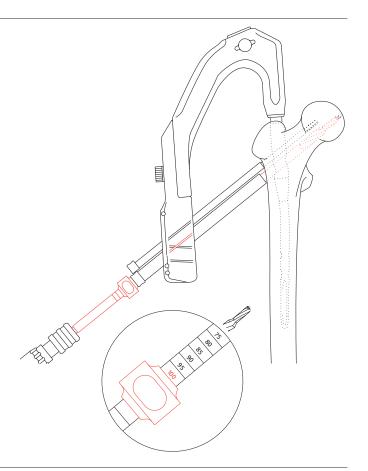
Now set the measured length on the 11.0 mm Reamer (357.045) by securing the Fixation Sleeve (357.046) in the appropriate position. The correct length is indicated on the side of the fixation sleeve facing the reamer tip.

Advance 11 mm reamer (357.044) over the 2.8 mm guide wire. Drill until the stop. Further drilling is prevented by the

fixation sleeve. Tapping is not required due to the self-tapping tip of the femoral neck screw.

Precautions:

- If the guide wire has been bent slightly during insertion, the drill can be guided over it using careful forward and backward movements.
- If the guide wire has been bent to a greater extent, it should be reinserted or replaced by a new guide wire, otherwise the tip of the drill may break.



15

Insert femoral neck screw

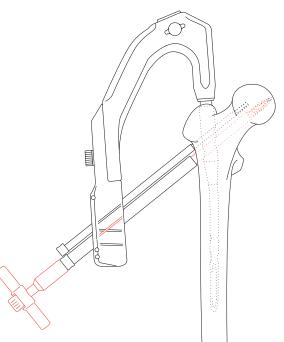
Assemble the Wrench for Femoral Neck Screw (357.053 consisting of: 357.054/357.051) and secure it tightly to the selected femoral neck screw.

Insert the femoral neck screw over the 2.8 mm guide wire up to the stop.

Remove the wrench for the femoral neck screw, if necessary using the Hexagonal Wrench (357.023).

Remove and discard the 2.8 mm guide wire of the femoral neck screw. Finally, remove both protection sleeves from the aiming arm.

Check under image intensifier that femoral neck screw is not inserted behind the lateral cortex.



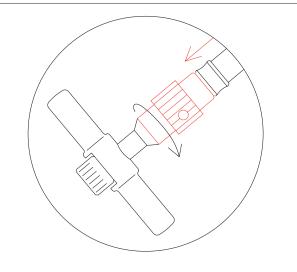
Option: Use of wrench for femoral neck screws with compression device

Assemble the Wrench for Femoral Neck Screw (357.048 consisting of: 357.050/357.051/357.052) and secure it tightly to the selected femoral neck screw. The Compression Nut (357.052) must be completely unscrewed in the lateral direction.

Insert the femoral neck screw over the 2.8 mm guide wire up to the stop.

If required, the Compression Nut (357.052) may be used to compress the fracture over the femoral neck screw. This

should be performed with great caution to prevent the screw from cutting out. Do not compress in osteoporotic bone.



16 Drill hole for distal locking

Distal locking is usually performed with a single locking bolt. For static interlocking use the cranial locking hole only; for dynamic interlocking the caudal locking hole. Subtrochanteric fractures may be double-locked. Secondary dynamization is possible by postoperative removal of the static locking bolt.

Make a stab incision and insert the green Drill Sleeve System (357.061/357.063/357.065) through the locking hole selected in the aiming arm until the bone is reached.

Remove the 4.0 mm Trocar (357.065) and drill through both cortices using the 4.0 mm Drill Bit (357.068).

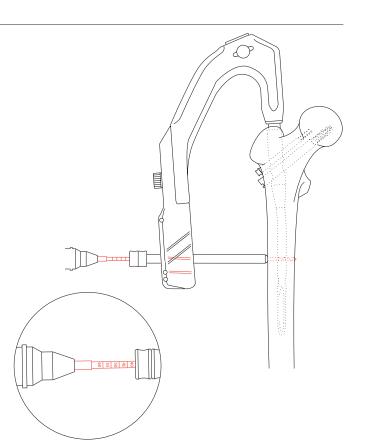
Read off the length of the required locking bolt directly from the drill marking. Ensure that the drill sleeve 8.0/ 4.0 has good bone contact.

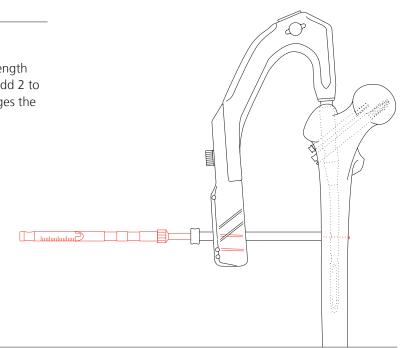
Precautions:

- Before distal locking, ensure that no diastasis has occurred intraoperatively. Healing may be delayed if the distal locking bolts are secured despite the presence of diastasis.
 - Ensure that all connections between the nail, insertion handle and aiming arm are still secure, otherwise the nail itself may be damaged during drilling of the distal locking holes.

Alternative method of measuring length

Remove the drill sleeve 8.0/4.0 and determine bolt length with the Depth Gauge for Locking Bolts (357.791). Add 2 to 4 mm to the reading to ensure that the thread engages the far cortex.





17 Insert locking bolt

Insert the locking bolt through the protection sleeve using the Large Hexagonal Screwdriver (314.260).

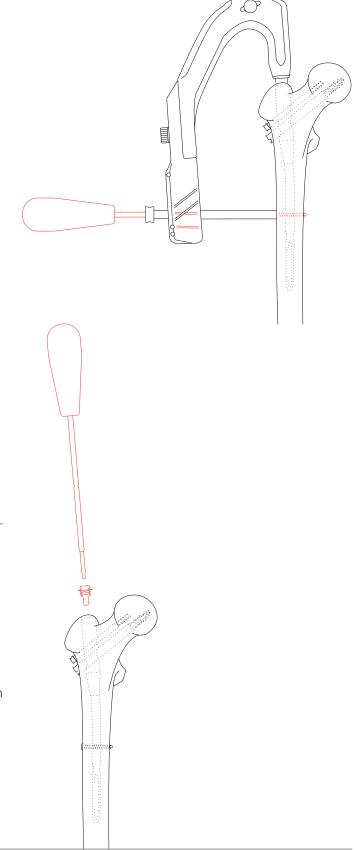
Remove the protection sleeve and the aiming arm. Then remove the insertion handle using the Hexagonal Wrench (357.023).

18 Insert end cap

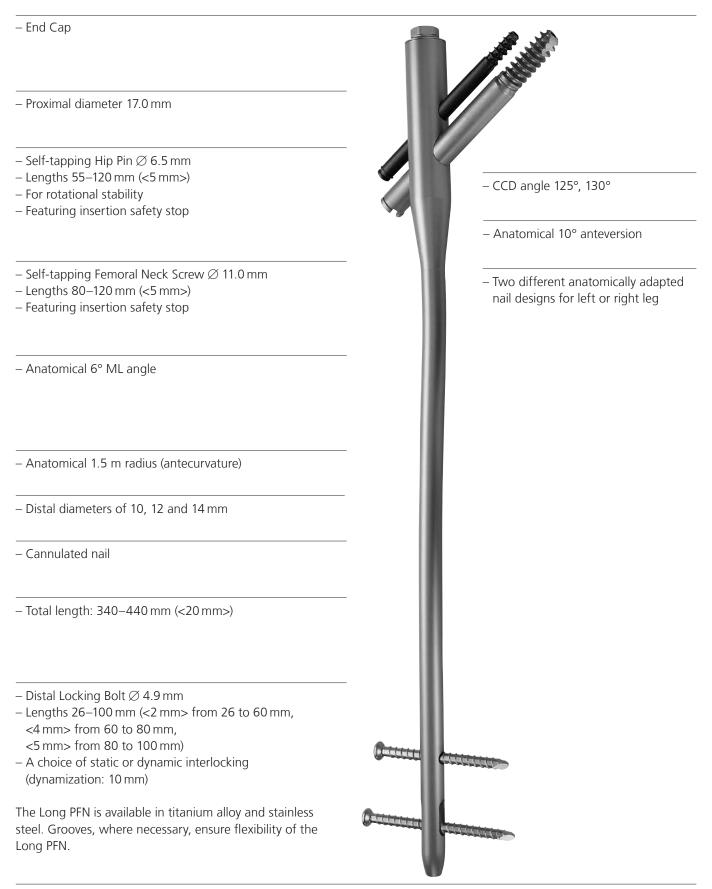
Align the end cap with the nail axis using the hexagonal screwdriver (314.260) in order to prevent tilting. Screw

the end cap completely onto the nail until its collar touches the proximal end of the nail.

In order to avoid losing the end cap and to facilitate insertion, the end cap can also be inserted through the Protection Sleeve 20.0/17.0 (357.001).



Implants for Long PFN



Preparation for Long PFN

Detailed surgical technique

This surgical technique is based on the PFN surgical technique for Standard/Short PFN. In order to follow the correct procedure, please refer to the respective steps in the standard technique. This part only shows the steps regarding insertion and distal interlocking of the Long PFN which differ from the standard technique.

Usually, the 130° nail is suitable for most indications. In some cases, however, the use of a 125° nail may be indicated.

Patient positioning

Please refer to the PFN standard surgical technique.

Determine CCD angle

Please refer to the PFN standard surgical technique.

Reduce fracture

Please refer to the PFN standard surgical technique. However, the special conditions of the very different fracture types have to be considered.

Determine nail length

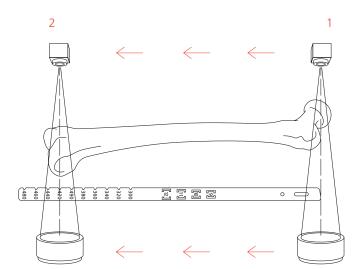
Position the image intensifier for an AP view of the proximal femur (1). With a long forceps, hold the Radiographic Ruler (357.590) alongside the lateral aspect of the thigh parallel to and at the same level as the femur. Adjust the C-arm so the beam is centred between the femur and ruler; this will reduce magnification errors. Adjust the ruler until the top is level with the tip of the greater trochanter. Mark the skin at the top of the ruler.

Move the image intensifier to the distal femur (2), place the proximal end of the ruler at the skin mark, and take an AP image of the distal femur. Verify fracture reduction. Read nail length directly from the ruler image, selecting the measurement that is at or just proximal to the physeal scar, or at the chosen insertion depth.

Consider the nail range of 340, 360, 380, 400, 420 and 440 mm.

Determine nail diameter

Please refer to the PFN standard surgical technique.







2. Read nail length

1. Position the ruler

Surgical technique for Long PFN

Approach

Please refer to the PFN standard surgical technique.

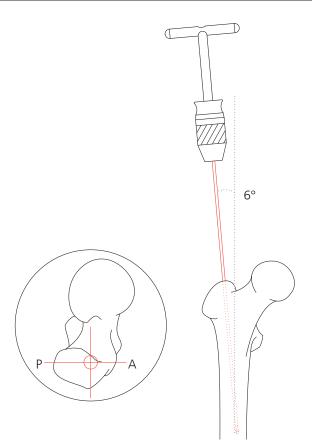
1

Determine nail insertion point and insert guide wire

In the AP view, the nail insertion point is normally found on the tip or slightly lateral to the tip of the greater trochanter in the curved extension of the medullary cavity.

The mediolateral angle of the implant is 6°. This means that the 2.8 mm Guide Wire (357.039) must be inserted laterally at an angle of 6° to the shaft. The guide wire can be inserted either manually with the Universal Chuck with T-Handle (393.100) or with a Compact[™] Air Drive and with the quick coupling for Kirschner wires.

In a lateral view, place the guide wire in the centre of the cavity.



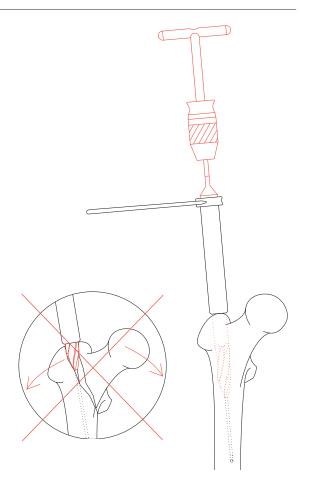
2 Open femur

Guide the 17.0 mm Cannulated Drill Bit (357.005) through the Protection Sleeve 20.0/17.0 (357.001) over the guide wire and ream manually with the Universal Chuck with T-Handle (393.100) as far as the stop on the protection sleeve.

Remove protection sleeve and guide wire. Do not re-use the guide wire.

Precaution: Particularly careful drilling is required with unstable multifragment fractures. Specifically, avoid varus displacement of the medial fragment by making sure that the hole is drilled both in the medial fragment and the lateral part of the femur.

Optional opening with reverse awl: See standard technique.



Ream medullary cavity with SynReam (Option)

If necessary, enlarge the femoral canal to the desired diameter using the medullary reamer system SynReam and the corresponding surgical technique (DSEM/TRM/0614/0103).

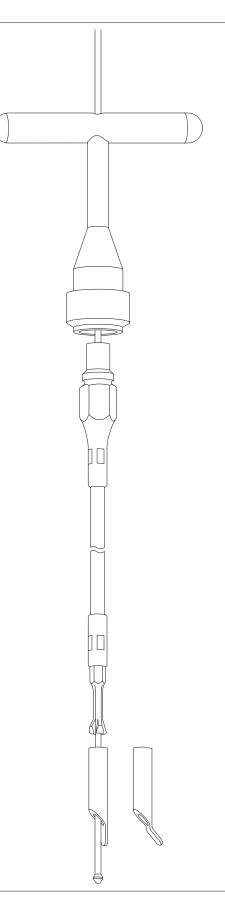
Use image intensification to confirm fracture reduction. Insert the reaming rod into the medullary canal to the desired insertion depth. The tip must be correctly positioned in the medullary canal since it determines the final distal position of the nail.

Reaming

3

Remove the reaming rod before locking the intramedullary nail. Starting with the 8.5 mm diameter reaming head, ream to a diameter of 0.5 mm to 1.5 mm greater than the nail diameter. Ream in 0.5 mm increments and advance the reamer with steady, moderate pressure. Do not force the reamer. Partially retract the reamer repeatedly to clear debris from the medullary canal.

Use the holding forceps to retain the reaming rod while reaming and to prevent it from rotating. Remove the reaming rod before locking the intramedullary nail.



Assemble instruments

Please refer to the PFN standard surgical technique.

Note: Choose the corresponding nail for left or right leg.

5

4

Insert long proximal femoral nail

If no reaming has been performed, the guide wire may help the insertion, but is usually not necessary.

Carefully insert the nail manually (be it directly over the Syn-Ream Reaming Rod \emptyset 2,5 mm [352.032 or 352.033] or not) as far as possible into the femoral opening. Slight twisting hand movements help insertion.

If the SynReam reaming rod is used, it does not need to be replaced by the guide wire for nails.

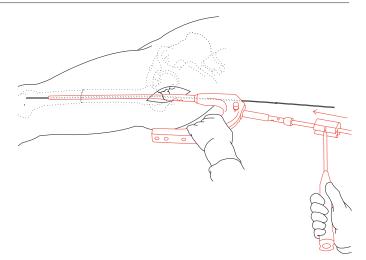
If necessary, insertion can be supported by light hammering blows. For this, insert the Thread Gland (357.013) into the insertion handle. Then mount the Hammer Guide (357.071), which is also used for nail extraction, through the protection plate firmly into the gland. Make sure the connection is very firm. Then use the Slotted Hammer (357.026) to support the insertion carefully. Then remove the guide wire.

Alternative

Insertion can be supported by light hammer blows with the Synthetic Hammer (399.505) directly on the mounted protection plate.

Precautions:

- Avoid unnecessary use of force and only hit the hammer guide or the protection plate. Do not hit the most proximal end of the hammer guide.
 - If too much force is needed for insertion, the nail should be removed and the femoral shaft should be reamed again.
 - It is important that the nail is always tightly connected to the insertion handle. This has to be checked especially after hammering.



Insert hip pin and femoral neck screw

Please refer to the PFN standard surgical technique and choose the 125° or 130° Aiming Arm (357.015/357.105 or 357.016/357.106) for the corresponding CCD-angle of the chosen nail.

7 Distal locking

6

Distal locking is usually performed with two locking bolts. For static interlocking, the caudal bolt is positioned at the proximal end of the locking slot, for dynamic interlocking it is positioned at the distal end of the locking slot. If immediate dynamization is required, only use the caudal locking slot. For secondary dynamization insert both locking bolts as described above and remove the static bolt at a later date.

Reconfirm reduction/alignment of the distal fragment.

Then use the Radiolucent Drive (511.300).

Align the image intensifier with the cranial hole in the nail until a perfect circle is visible in the centre of the screen. Make a stab incision at the incision point.



Oblique (incorrect)



Round (correct)

Under image intensification, insert the tip of the 4.0 mm Drill Bit with Coupling for RDL into the incision and place the bit oblique to the X-ray beam until the tip is centred in the locking slot.

Tilt the drive until the drill bit is in line with the beam and appears as a radiopaque solid circle in the centre of the outer ring. The drill bit will nearly fill in the locking hole image. Hold the drill in this position and drill through both cortices.

Measure the needed locking bolt length using the Depth Gauge (357.791), adding 2–4 mm to the reading to ensure thread engagement in the far cortex.

Insert the bolt using the Large Hexagonal Screwdriver (314.260).

Then proceed the same way for the second distal locking bolt. For static interlocking place the caudal locking bolt in the proximal position of the locking slot, for dynamic interlocking in the distal position to allow dynamization.

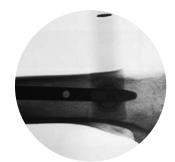
Note: If the Radiolucent Drive (511.300) is not available, perform distal interlocking in standard freehand technique using the 4.0 mm Drill Bit (357.068).



Determine incision point



Center drill bit in locking hole



Align drill bit

8 Insert end cap

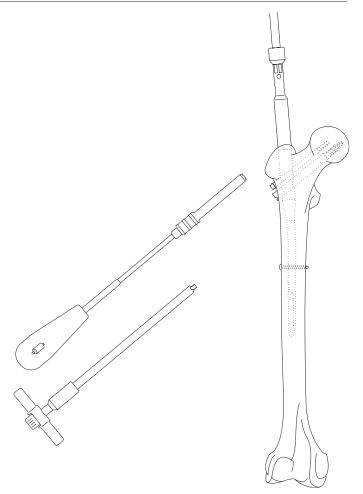
Please refer to the PFN standard surgical technique.

1

Remove femoral neck screw and hip pin

Having made an incision through the old scar, the neck screw, hip pin, locking bolt and nail may be localized using
palpation or the image intensifier. In some cases, the instruments have a better grip on the neck screw, hip pin, locking bolt and nail if a Ø 2.8 mm Guide Wire (357.039) is inserted. First remove the end cap and insert the Hammer Guide (357.071) into the proximal nail end. Ensure that the Hammer Guide (357.071) is firmly seated in the nail; the 4.5 mm Pin Wrench (321.170) may be used for this purpose. Only then may the femoral neck screw, the hip pin and the locking bolts be removed by using the insertion instruments. To extract the hip pin, the Extraction Holding Sleeve for Hip Pin (357.073) is required additionally.

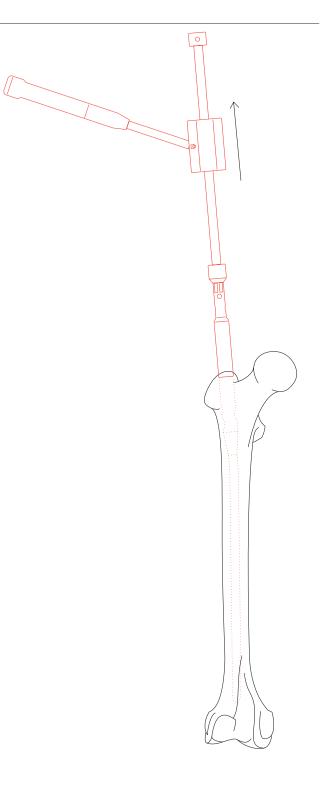
Precaution: If soft tissue situation is difficult, the guide rod for nail extraction can be mounted after removal of all but one locking bolt in order to prevent nail rotation in the medullary cavity.



2 Extract proximal femoral nail

Ensure that the Hammer Guide (357.071) is firmly seated in the nail. To remove the nail, clip the Slotted Hammer (357.026) on to the hammer guide. Now extract the nail with slight hammer blows.

Note: If the removal of the nail is not possible with the standard instruments use the special instruments from the Proximal Femoral Nail Removal Set for PFN, TFN and PFNA/ PFNA-II (01.010.180) and the corresponding surgical technique (DSEM/TRM/1214/0253).



Intraoperative and postoperative cleaning

The cannulations of the instruments must be cleaned intraoperatively using the \varnothing 2.8 mm Cleaning Stylet for Cannulated Instruments (319.460) or the long Cleaning Stylet (357.009/length 450 mm).

Postoperatively the instruments are cleaned with the Cleaning Stylet (319.460) and the \varnothing 2.9 mm Cleaning Brush for Cannulated Instruments (319.240).

Torque, Displacement and Image Artifacts according to ASTM F2213-06, ASTM F2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F 2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.



Synthes GmbH Eimattstrasse 3 4436 Oberdorf Switzerland Tel: +41 61 965 61 11 Fax: +41 61 965 66 00 www.depuysynthes.com

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

All surgical techniques are available as PDF files at www.depuysynthes.com/ifu

