SURGICAL TECHNIQUE

PROXIMAL FEMORAL NAIL

SYSTEM OVERVIEW

NAILS	
PROXIMAL FEMORAL NAIL (P.F.N), (RIGHT) (9.0 mm) • Catalogue Number: Stainless Steel: SS 205 Titanium: TT 205 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 34cm to 44cm • Diameter: 9mm	
PROXIMAL FEMORAL NAIL (P.F.N), (RIGHT) (10.0 mm) • Catalogue Number: Stainless Steel: SS 205 Titanium: TT 205 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 34cm to 44cm • Diameter: 10mm	
PROXIMAL FEMORAL NAIL (P.F.N), (RIGHT) (11.0 mm) • Catalogue Number: Stainless Steel: SS 205 Titanium: TT 205 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 34cm to 44cm • Diameter: 11mm	
PROXIMAL FEMORAL NAIL (P.F.N), (LEFT) (9.0 mm) • Catalogue Number: Stainless Steel: SS 206 Titanium: TT 206 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 34cm to 44cm • Diameter: 9mm	

PROXIMAL FEMORAL NAIL (P.F.N), (LEFT) (10.0 mm) • Catalogue Number: Stainless Steel: SS 206 Titanium: TT 206 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 34cm to 44cm • Diameter: 10 mm	
PROXIMAL FEMORAL NAIL (P.F.N), (LEFT) (11.0 mm) • Catalogue Number: Stainless Steel: SS 206 Titanium: TT 206 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 34cm to 44cm • Diameter: 11 mm	
PROXIMAL FEMORAL NAIL (P.F.N), (SHORT) 135° 25cm • Catalogue Number: Stainless Steel: SS 207 Titanium: TT 207 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 25cm • Diameter: ø 09.0 mm, ø 10.0 mm, ø 11.0 mm, ø 12.0 mm	
PROXIMAL FEMORAL NAIL (P.F.N), (SHORT) 130° 25cm • Catalogue Number: Stainless Steel: SS 207 Titanium: TT 207 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 25cm • Diameter: ø 09.0 mm, ø 10.0 mm, ø 11.0 mm, ø 12.0 mm	
CAP FOR PROXIMAL FEMORAL NAIL (P.F.N) • Catalogue Number: Stainless Steel: SS 200-004 Titanium: TT 200-004	

4.9 mm INTER-LOCKING SCREW • Catalogue Number: Stainless Steel: SS 214 Titanium: TT 214 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20mm to 90mm • Diameter: 4.9mm	
6.4 mm PROXIMAL FEMORAL SCREW (P.F.N) • Catalogue Number: Stainless Steel: SS 215 Titanium: TT 215 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 60mm to 120mm • Diameter: 6.4mm	
8.0 mm PROXIMAL FEMORAL SCREW (P.F.N) • Catalogue Number: Stainless Steel: SS 216 Titanium: TT 216 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 60mm to 120mm • Diameter: 8.0mm	

GUIDE WIRE (SIMPLE) • Catalogue number- Stainless Steel 316L: SS 291-020 • Available in Stainless Steel 316L • Diameter: 2.0mm • Length: 16”	
GUIDE WIRE (THREADED) • Catalogue number- Stainless Steel 316L: SS 291-120 • Available in Stainless Steel 316L • Diameter: 2.0mm • Length: 16”	
GUIDE WIRE LONG SIMPLE • Catalogue number- Stainless Steel 316L: SS 292-025 • Available in Stainless Steel 316L • Diameter: 2.5mm • Length: 40”	
GUIDE WIRE LONG BIDED • Catalogue number- Stainless Steel 316L: SS 292-125 • Available in Stainless Steel 316L • Diameter: 2.5mm • Length: 40”	

STEINMANN PIN (3.5 mm) • Catalogue number- Stainless Steel 316L: SS 228 Titanium Grade 5: TT 228 • Available in Stainless Steel 316L & Titanium Grade 5 • Length: 125mm to 300mm • Diameter: 3.5 mm	

INSTRUMENT SET DETAILS

SIS 118	**P.F.N. Instruments Set**
SIS 118-001	Threaded Bolt
SIS 118-002	Small Hammer Unit With Nut
SIS 118-003	Jig (135')
SIS 118-004	Extractor Rod
SIS 118-005	Round Hammer
SIS 118-006	Protection Sleeve 12mm
SIS 118-007	Protection Sleeve 10mm
SIS 118-008	Drill Sleeve for 4.0mm Drill
SIS 118-009	Guide Wire Sleeve 2.0mm For 12mm
SIS 118-010	Guide Wire Sleeve 2.0mm For 10mm
SIS 118-011	Pointer (Long)
SIS 118-012	T-Handle (Wrench)
SIS 118-013	T- Handle for Q.C Drill Bit/Tap
SIS 118-014	Spanner Irdinary (12 X 13/1, 16 X 17/1)
SIS 118-015	C.C. Screw Driver 5.0mm (250mm)
SIS 118-016	Guide Wire Simple 2.0mm X 16"
SIS 118-017	Guide Wire Threaded 2.0mm X 16"
SIS 118-018	C.C. Drill Bits long With Q.C for 8.0mm Screw
SIS 118-019	C.C. Drill Bits long With Q.C for 6.4mm Screw
SIS 118-020	Screw Driver 4.5mm Hex (250mm)
SIS 118-021	Drill Bits 4.0mm long 10"
SIS 118-022	Depth Guage (110MM)
SIS 118-023	Solhapur Sleeve (15MM)
SIS 118-024	Proximal Reamer (14MM)
SIS 118-025	Bone AWL Straight

PROXIMAL FEMORAL NAIL (RIGHT):

Note: Define code for SS 316L/SS 205, Titanium /TT 205, SS 316 LVM/LM 205

Screw places: 8mm, 6.4mm, and 4.9mm

PROXIMAL FEMORAL NAIL (LEFT):

Note: Define code for SS 316L/SS 206, Titanium /TT 206, SS 316 LVM/LM 206

Screw places: 8mm, 6.4mm, and 4.9mm

INDICATIONS:

Proximal femoral nail is intended to treat stable and unstable proximal femoral fractures including pertrochanteric fractures, intertrochanteric fractures, and high subtrochanteric fractures.

CONTRAINDICATIONS:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected. Relative Contraindications Indications, Precautions & Contraindications Indications
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

ADVERSE REACTIONS:

- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area

PRECAUTIONS:

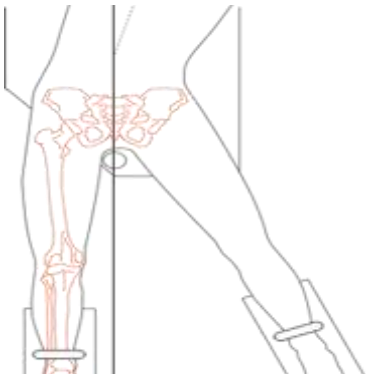
An implant shall never be reused. Previous stresses may have created imperfections which can lead to device failure. Instruments shall be inspected for wear or damage prior to usage. Protect implant appliances against scratching and nicking. Such stress concentrations can lead to failure.

SINGLE BRAND USAGE:

Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

SURGICAL TECHNIQUE:

1. **Patient positioning**



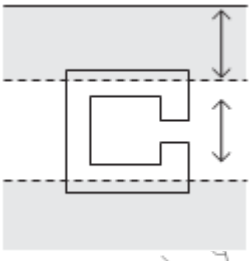
Position patient supine on an extension table or a radiolucent operating table. Position the C-arm of the image intensifier in such a way that it can visualize the proximal femur exactly in the lateral and AP planes.

For unimpeded access to the medullary cavity, abduct the upper part of the body by about 10–15º to the contralateral side (or adduct the affected leg by 10–15º).

2. **Reduce fracture:**

If possible, carry out closed reduction of the fracture under image intensifier control. Exact reduction and secure fixation of the patient to the operating table are essential for easy handling and a good surgical result.

3. **Determine nail diameter:**



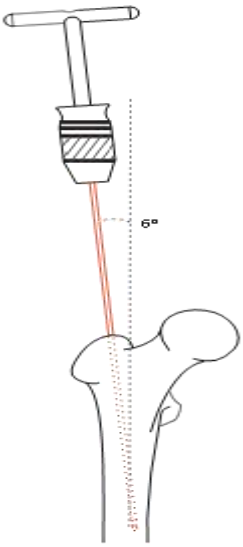
Under image intensifier control, place the Measuring Device on the femur and position the square marking over the isthmus. If the transition to the cortex is still visible to the left and right of the marking, the corresponding nail diameter may be used.

4. **Approach:**

Palpate the greater trochanter.

Make a 5cm incision approximately 5 to 8cm 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 the fibres.

5. 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.

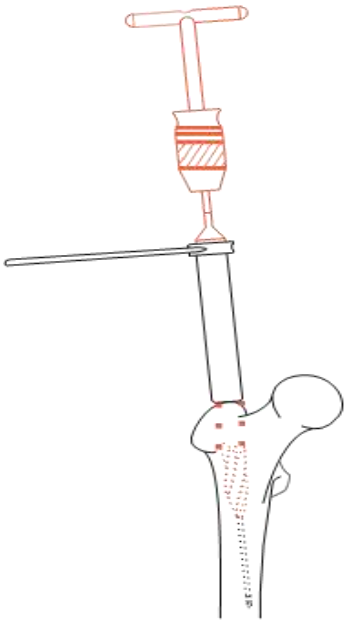
The mediolateral angle of the implant amounts to 6º. This means that the 2.5 mm Guide Wire must be inserted laterally at an angle of 6º to the shaft. The guide wire can be inserted manually with the Universal Chuck with T-Handle and the quick coupling for Kirschner wires

In lateral view, place the guide wire in the centre of the medullary cavity to a depth of about 15cm.

Percutaneous technique: Insert guide wire through the Protection Sleeve and the Drill Sleeve. Then remove the drill sleeve.

Note:To ensure correct position of guide wire, position a nail ventrally on the femur and check radiographially.

6. Opening the femur:

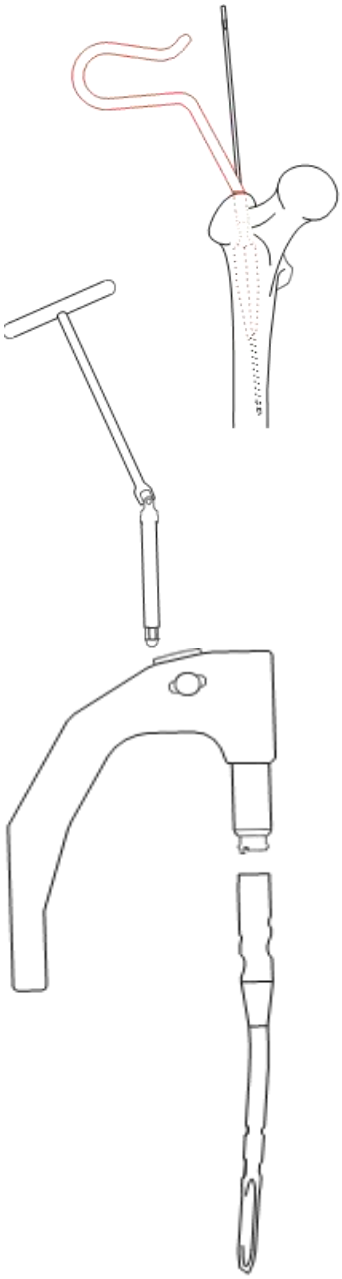


Guide the cannulated 17.0mm Drill Bit over the guide wire through the protection sleeve and ream manually with the Universal Chuck with T-Handle as far as the stop on the protection sleeve.

Remove protection sleeve and guide wire. Dispose of the guide wires, do not reuse them

OPTION: Opening with reverse awl:

Open the femur or enlarge the entry point with the Reverse Awl. Use the Tissue Protector to spare soft tissues. Drive the awl over the guide wire into the femur until the marking on the awl shaft is level with the trochanter tip.



7. Assemble instruments:

Guide the Connecting Screw through the Insertion Handle and secure the nail tightly to the insertion handle using the Hexagonal Socket. 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.

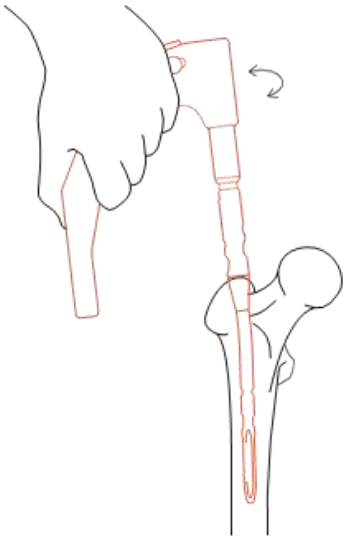
8. Insertion of standard PFN:

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 on the mounted protection shield of the insertion handle.

Caution: Avoid unnecessary use of force and only hit the protection plate. In smaller medullary canals, ream the distal part to at least 10mm.

It is important that the nail is always tightly connected to the insertion handle.



9. Insertion of femoral neck screw and hip pin:

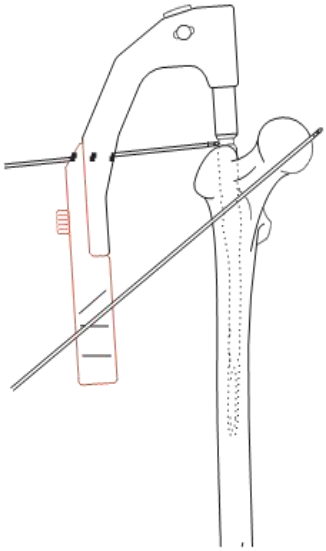
Insert the screws using the colour-coded drill sleeve systems consisting of protection sleeve, drill sleeve and trocar.

Tightly secure the appropriate Aiming Arm to the insertion handle.

Note:

The position of the nail can be verified by placing a guide wire on the surface of the insertion handle. The position of the end of the nail can be checked by inserting a wire through the insertion handle.

To ensure the correct ante-version of the implant, an additional guide wire can be inserted ventral to the femoral neck into the femoral head.

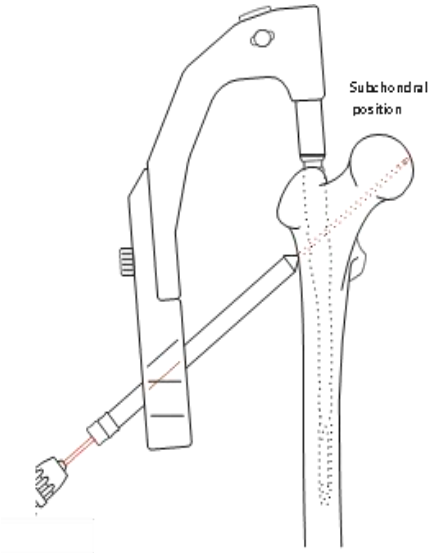


10. Insertion of guide wire for femoral neck screw:

Make a stab incision and insert the pink Drill Sleeve System through the aiming arm to the bone. Mark the femur and remove the trocar.

Insert a new 2.5 mm Guide Wire through the drill sleeve, check direction and position under image intensifier in AP and lateral views.

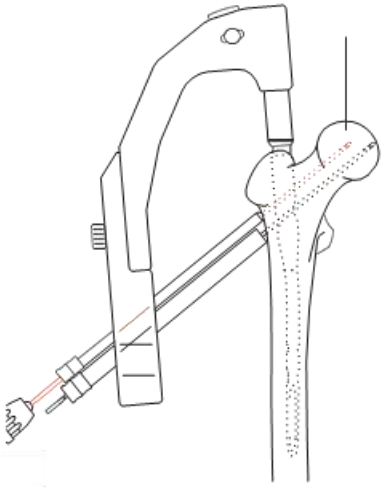
Choose a position in the caudal area of the femoral head so that both proximal screws can be inserted. Insert the guide wire 5 mm deeper into the femoral head than the planned femoral head screw. The final position of the guide wire should be in the lower half of the femoral neck. In lateral view, the wire should be positioned in the centre of the femoral neck.



11. Insertion of guide wire for hip pin:

Insert the blue Drill Sleeve System through the blue drill hole on the aiming arm to the bone.

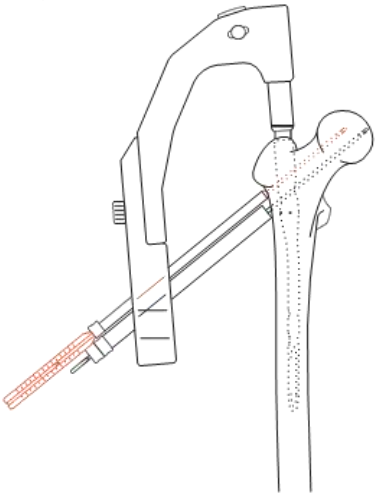
Then remove the trocar and insert a second, new 2.5 mm guide wire through the drill sleeve into the bone. The tip of the guide wire should be positioned at least 20mm medial of the fracture line and 5mm deeper than the planned hip pin, but approximately 15–20mm less deep than the planned femoral neck screw.



12. Measure length of hip pin

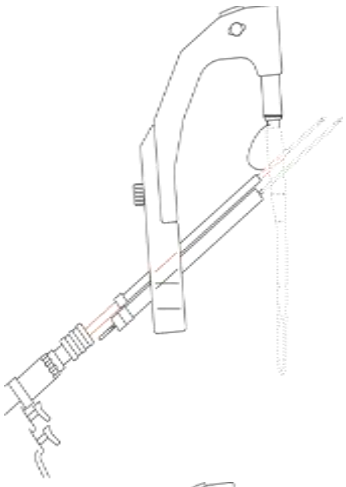
It is recommended to start with the insertion of the hip pin to prevent possible rotation of the medial fragment when inserting the femoral neck screw.

Remove the drill sleeve. Guide the Direct Measuring Device through the protection sleeve to the bone and determine the length of the required hip pin. The length of this pin is indicated on the measuring device and calculated to end 5mm before the tip of the guide wire.



13. Drill hole for hip pin:

Advance the 6.5 mm cannulated drill bit over the 2.5 mm guide wire. Drill to the stop. As the tip of the hip pin is self-tapping, usually no further tapping and drilling is needed.



14. Procedure in hard bone:

In hard or young bone, further drilling and tapping with the cannulated 6.5mm Tap is recommended up to the length of the hip pin previously measured.

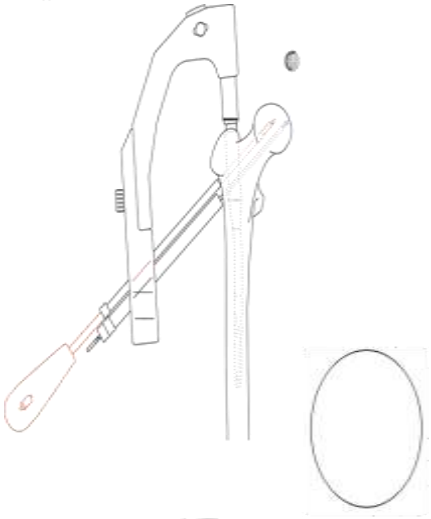
15. Insertion of hip pin

Use the cannulated Hexagonal Screwdriver to insert the selected hip pin over the guide wire to the stop.

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

Caution:

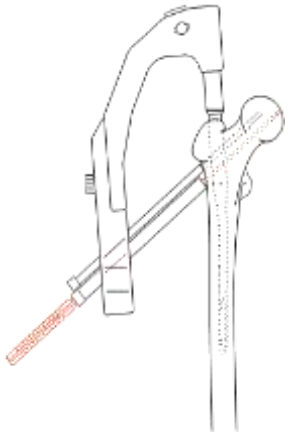
Do not insert the hip pin with undue force. Ensure that the lateral end of the hip pin clearly protrudes from the lateral cortex. Check under image intensification that hip pin is not inserted too far.



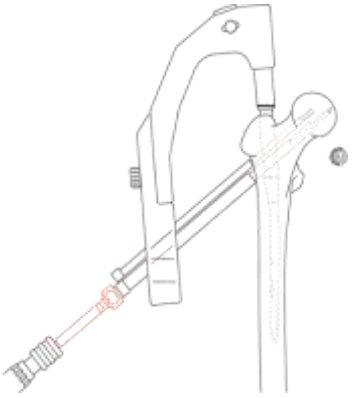
16. Measure length of femoral neck screw:

Remove the pink Drill Sleeve. Guide the Direct Measuring Device over the second 2.5 mm guide wire through the pink protection sleeve until it touches bone, and determine the length of the required femoral neck screw. The correct screw length is indicated on the measuring device and calculated to end approx. 5mm before the tip of the guide wire.

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

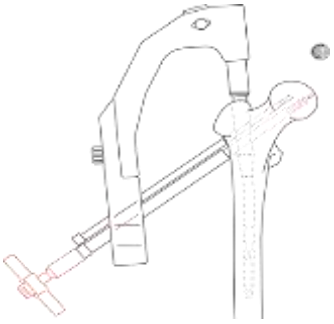


17. Drill hole for femoral neck screw



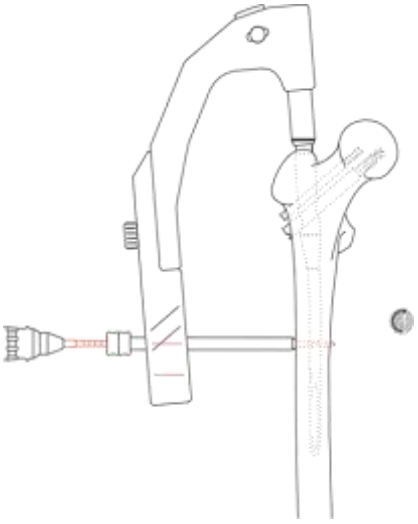
Advance the 11.0mm reamer over the 2.5 mm guide wire. Drill to the stop. The fixation sleeve prevents further drilling.
Tapping is not required due to the self-tapping tip of the femoral neck screw.
Note:
If the guide wire has been bent slightly during insertion, the reamer can be guided over it using 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 one. However, in some cases it is possible to cautiously complete reaming without a guide wire.

18. Insertion of femoral neck screw



Assemble the Wrench for Femoral Neck Screw and secure it tightly to the selected femoral neck screw. Insert the femoral neck screw over the 2.5 mm guide wire to the stop.
Remove the wrench for the femoral neck screw, if necessary using the Hexagonal Socket.
Remove and discard the 2.5 mm guide wire of the femoral neck screw. Finally, remove both protection sleeves from the aiming arm.
Check under image intensification that the femoral neck screw protrudes slightly over the lateral cortex.

19. Drill hole for distal locking

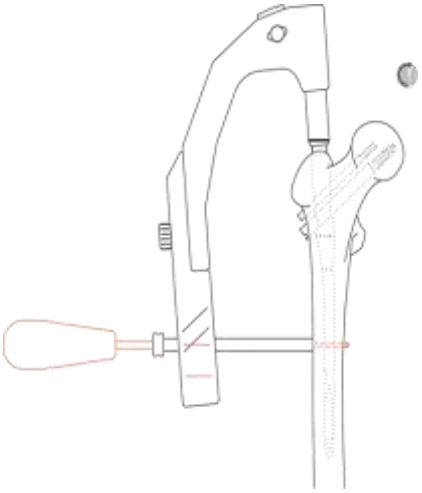


Distal locking is usually performed with a single locking bolt. For static interlocking Use the cranial locking hole only for static interlocking, and the caudal locking hole for dynamic interlocking. Sub-trochanteric fractures may be double-locked. Postoperative removal of the static locking bolt allows secondary dynamization.
Make a stab incision and insert the green Drill Sleeve System through the locking hole selected in the aiming arm to the bone.
Remove the green 4.0mm Trocar and drill through both cortices using the 4.0mm Drill Bit.
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.

20. Insertion of locking bolt

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

Remove the protection sleeve and the aiming arm. Then remove the insertion handle using the Hexagonal Socket



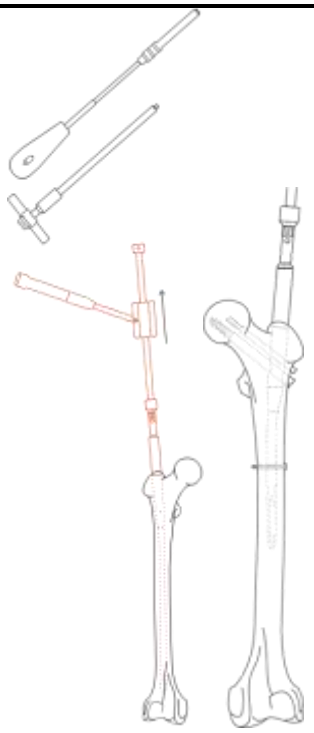
21. Insertion of End Cap

Align the end cap with the nail axis using the hexagonal screwdriver in order to prevent tilting. Screw the end cap completely onto the nail until its collar touches the proximal end of the nail.

IMPLANT REMOVAL:

1. Remove femoral neck screw and hip pin

Having made an incision through the old scar, the screws can be localized using palpation or the image intensifier. In some cases, the instruments have a better grip on the screws if a 2.5 mm Guide Wire is inserted. First remove the end cap and insert the Guide Rod into the proximal nail end. Only then may the femoral neck screw, the hip pin and the locking bolt be removed by using the insertion instruments. To extract the hip pin, the Extraction Holding Sleeve for Hip Pin is required additionally.



Note: If the 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. Remove the last locking bolt.

2. Extract nail

To remove the nail, mount the Slotted Hammer onto the guide rod. Ensure that the guide rod is firmly seated in the nail; the 4.5mm Pin Wrench may be used for this purpose. Now extract the nail with slight hammer blows.

CAUTION:

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore reuses of implants are strictly not recommended.

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

MRI SAFETY INFORMATION:

Samay Surgical implants are manufactured from Titanium Gr.5 and SS316L material and both are non-magnetic material, hence it do not pose any safety risk.

Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment.

Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.

Samay Surgical implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI.

PACKAGING MATERIAL DISPOSAL:

The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such ways that keep out of reach of children and stray animals.

The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks.

The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

Proximal Femoral Nail (P.F.N), (Right)

Note : Define Code for S.S. 316L/SS 205, Titanium/TT 205, S.S. 316LVM/LM 205
Screw Places : 8.0mm/6.4mm/4.9mm

Code No. S.S. 316L	Code No. S.S. 316L	Length	Angled
Dia. (9.0mm)	Dia. (10.0mm)		
SS 205-034	SS 205-134	34cm	135°
SS 205-036	SS 205-136	36cm	135°
SS 205-038	SS 205-138	38cm	135°
SS 205-040	SS 205-140	40cm	135°
SS 205-042	SS 205-142	42cm	135°
SS 205-044	SS 205-144	44cm	135°

Proximal Femoral Nail (P.F.N), (Left)

Note : Define Code for S.S. 316L/SS 206, Titanium/TT 206, S.S. 316LVM/LM 206
Screw Places : 8.0mm/6.4mm/4.9mm

Code No. S.S. 316L	Code No. S.S. 316L	Length	Angled
Dia. (9.0mm)	Dia. (10.0mm)		
SS 206-034	SS 206-134	34cm	135°
SS 206-036	SS 206-136	36cm	135°
SS 206-038	SS 206-138	38cm	135°
SS 206-040	SS 206-140	40cm	135°
SS 206-042	SS 206-142	42cm	135°
SS 206-044	SS 206-144	44cm	135°

Proximal Femoral Nail (P.F.N), (Short) 25cm

Screw Places : 8.0mm/6.4mm/4.9mm

Code No. S.S. 316L	Code No. Titanium	Dia.	Angled
SS 207-009	TT 207-009	9mm	130°
SS 207-010	TT 207-010	10mm	130°
SS 207-011	TT 207-011	11mm	130°
SS 207-012	TT 207-012	12mm	130°
SS 207-013	TT 207-013	13mm	130°
SS 207-014	TT 207-014	14mm	130°
SS 207-109	TT 207-109	9mm	135°
SS 207-110	TT 207-110	10mm	135°
SS 207-111	TT 207-111	11mm	135°
SS 207-112	TT 207-112	12mm	135°
SS 207-113	TT 207-113	13mm	135°
SS 207-114	TT 207-114	14mm	135°

4.9mm Inter-Locking Screw

Code No. S.S. 316L	Code No. Titanium	Length
SS 214-020	TT 214-020	20mm
SS 214-022	TT 214-022	22mm
SS 214-024	TT 214-024	24mm
SS 214-026	TT 214-026	26mm
SS 214-028	TT 214-028	28mm
SS 214-030	TT 214-030	30mm
SS 214-032	TT 214-032	32mm
SS 214-034	TT 214-034	34mm
SS 214-036	TT 214-036	36mm
SS 214-038	TT 214-038	38mm
SS 214-040	TT 214-040	40mm
SS 214-042	TT 214-042	42mm
SS 214-044	TT 214-044	44mm
SS 214-046	TT 214-046	46mm
SS 214-048	TT 214-048	48mm
SS 214-050	TT 214-050	50mm
SS 214-052	TT 214-052	52mm
SS 214-054	TT 214-054	54mm
SS 214-056	TT 214-056	56mm
SS 214-058	TT 214-058	58mm
SS 214-060	TT 214-060	60mm
SS 214-062	TT 214-062	62mm
SS 214-064	TT 214-064	64mm
SS 214-066	TT 214-066	66mm
SS 214-068	TT 214-068	68mm
SS 214-070	TT 214-070	70mm
SS 214-075	TT 214-075	75mm
SS 214-080	TT 214-080	80mm

6.4mm Proximal Femoral Screw (P.F.N)

Code No. S.S. 316L	Code No. Titanium	Length
SS 215-060	TT 215-060	60mm
SS 215-065	TT 215-065	65mm
SS 215-070	TT 215-070	70mm
SS 215-075	TT 215-075	75mm
SS 215-080	TT 215-080	80mm
SS 215-085	TT 215-085	85mm
SS 215-090	TT 215-090	90mm
SS 215-095	TT 215-095	95mm
SS 215-100	TT 215-100	100mm
SS 215-105	TT 215-105	105mm
SS 215-110	TT 215-110	110mm
SS 215-115	TT 215-115	115mm
SS 215-120	TT 215-120	120mm

8.0mm Proximal Femoral Screw (P.F.N)

Code No. S.S. 316L	Code No. Titanium	Length
SS 216-060	TT 216-060	60mm
SS 216-065	TT 216-065	65mm
SS 216-070	TT 216-070	70mm
SS 216-075	TT 216-075	75mm
SS 216-080	TT 216-080	80mm
SS 216-085	TT 216-085	85mm
SS 216-090	TT 216-090	90mm
SS 216-095	TT 216-095	95mm
SS 216-100	TT 216-100	100mm
SS 216-105	TT 216-105	105mm
SS 216-110	TT 216-110	110mm
SS 216-115	TT 216-115	115mm
SS 216-120	TT 216-120	120mm

Implants Certified by: CE XXXX

Instruments Certified by Self Declaration : CE

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