APIS™

Femur Reconstruction Nail System

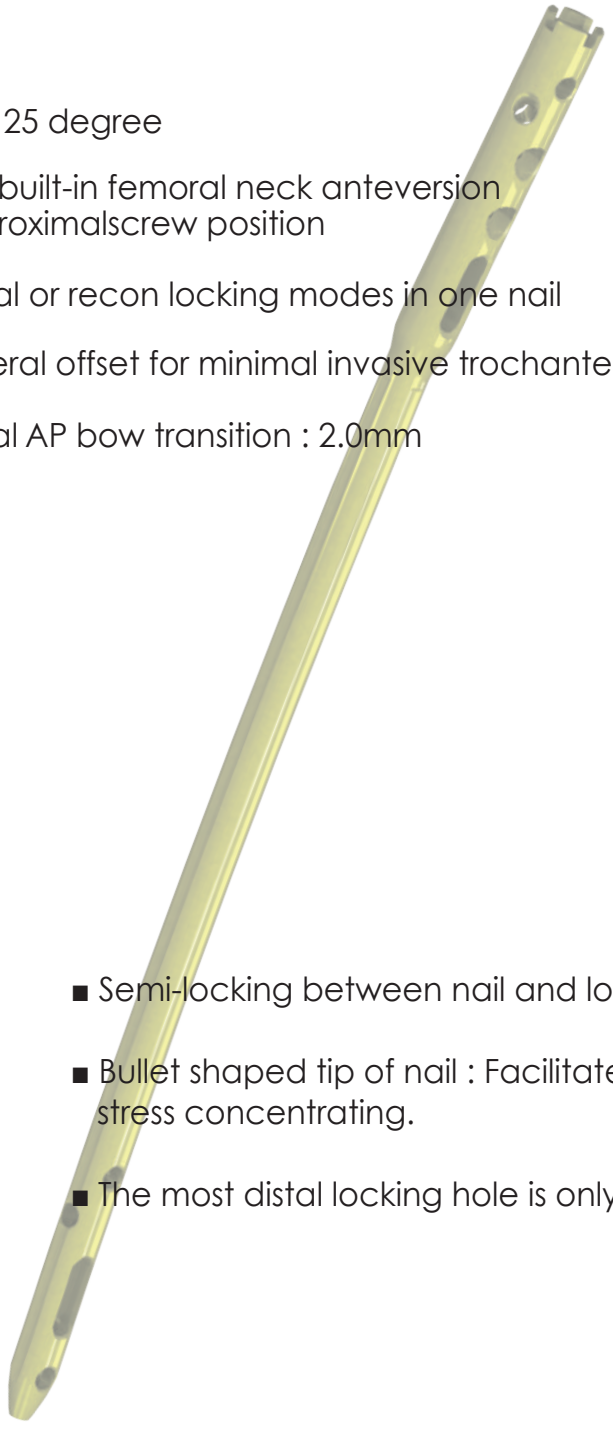
TDM

Advanced Principal Implant System

Contents

Product Feature

- Neck angle 125 degree
- 10 degree of built-in femoral neck anteversion for optimal proximal screw position
- Allows femoral or recon locking modes in one nail
- 4 degree lateral offset for minimal invasive trochanteric entry
- Proximal-distal AP bow transition : 2.0mm



- Semi-locking between nail and locking screw
- Bullet shaped tip of nail : Facilitates nails insertion and minimizes stress concentrating.
- The most distal locking hole is only 10mm away from end of nail

■ Unique five-hole proximal locking configuration
- Two lag screw hole
- One oblique hole (less trochanteric end point)
- One lateral static hole
- One dynamic hole

■ Four–hole distal locking options
- Two L/M static hole
- One L/M dynamic hole
- One A/P static hole

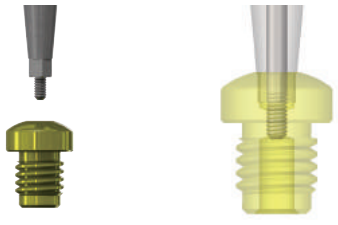
■ Static and dynamic distal and proximal locking

■ Small distance (18mm) between two 6.5mm lag screw
Two options 6.5m Lag screws
(cannulated and non-cannulated)

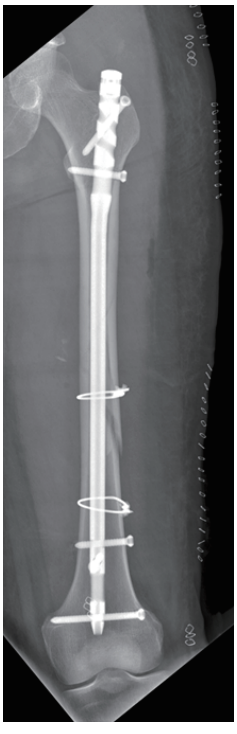
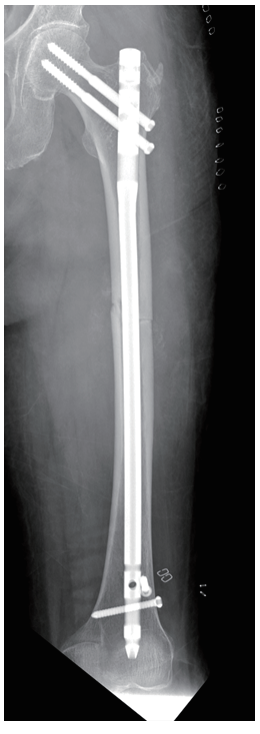
18mm

- Semi-locking between nail and locking screw

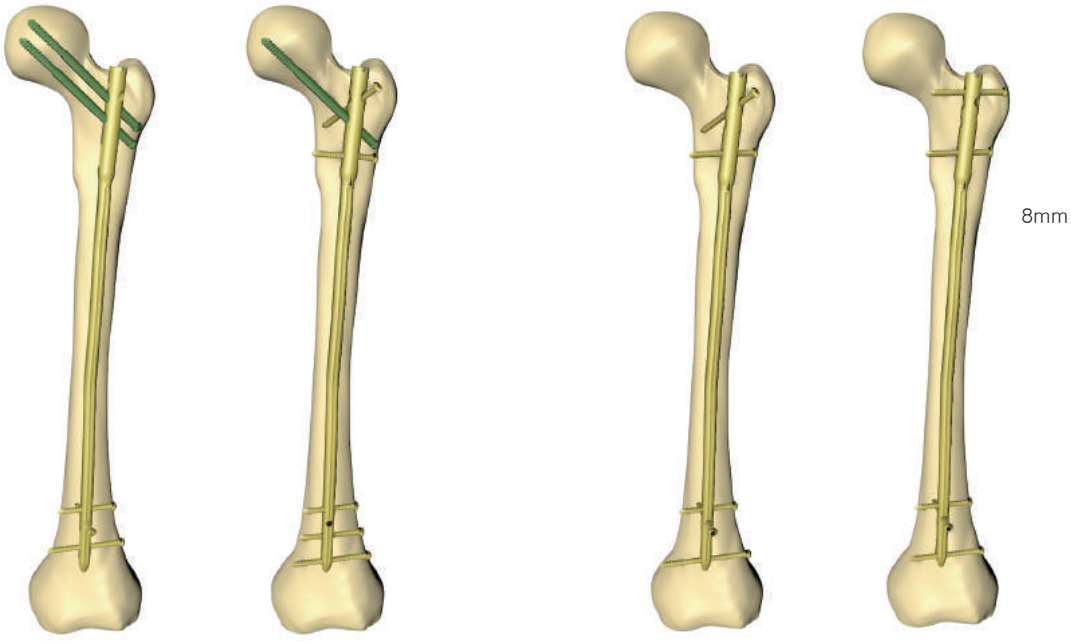
- Cap holding screwdriver for easy insertion



Clinical Case

Nail locking Options (Recon mode or Standard Mode)



Recon Locking

Standard Locking

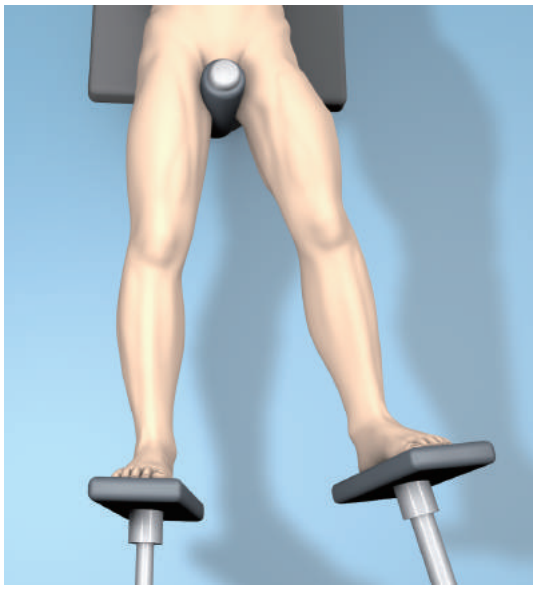
Indication

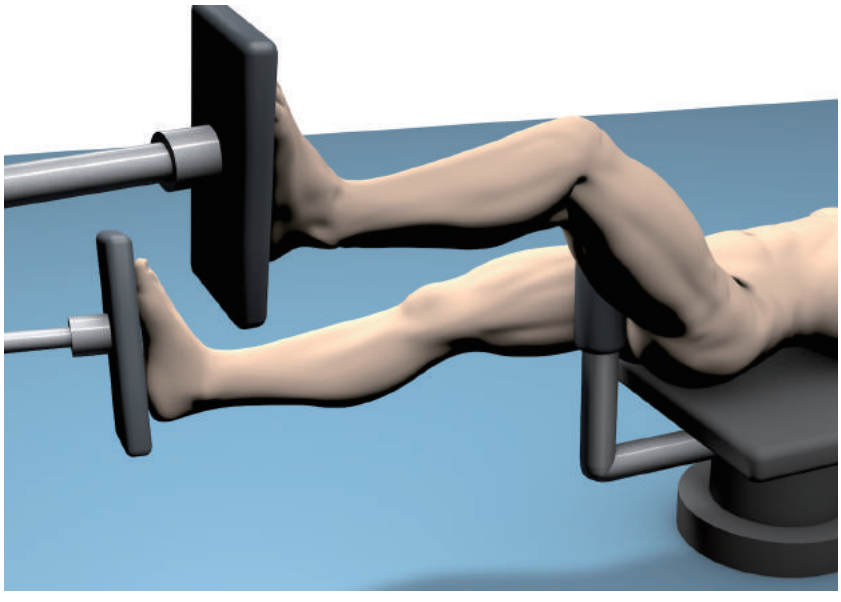
The fractures of the femur, including intertrochanteric Basi/trans-cervical femoral neck fractures and subtrochanteric, ipsilateral femoral neck/shaft fractures, stable and unstable shaft fractures, segmental fractures nonunions and malunions, polytrauma, reconstructions following tumor resection and bone lengthening and shortening.

Surgical Procedure

Patient Positioning

After anesthesia has been administered, the patient should be placed on either the supine or lateral decubitus poistioning on the table. The foot of the affected limb in placed in a foot holder or a pin is inserted through calcaneus for traction purposed, the unaffected limb is extended below and away from the affected limb or flexed and placed in a leg holder. To insure unimpeded access to the medullary cavity,abduct the upper body almost 10-15 degree to the contralateral side. (or adduct the affected limb by 10-15 degree)



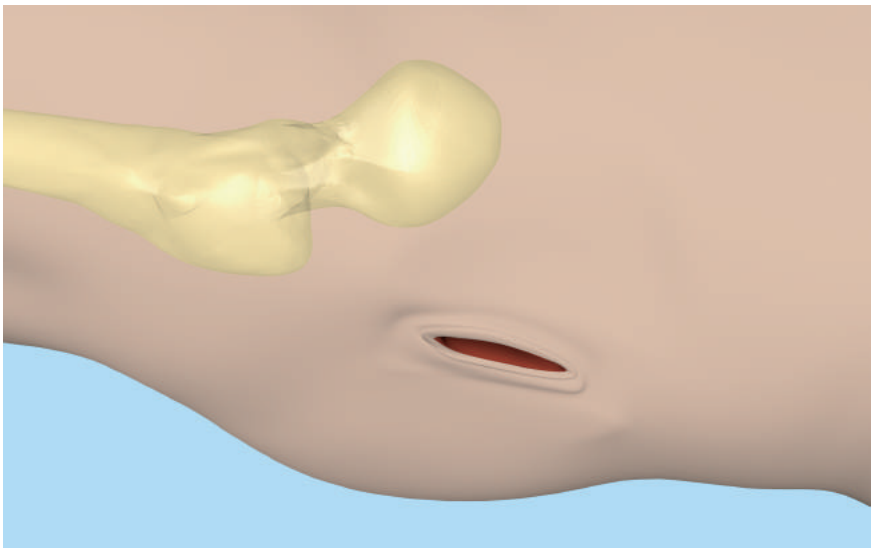


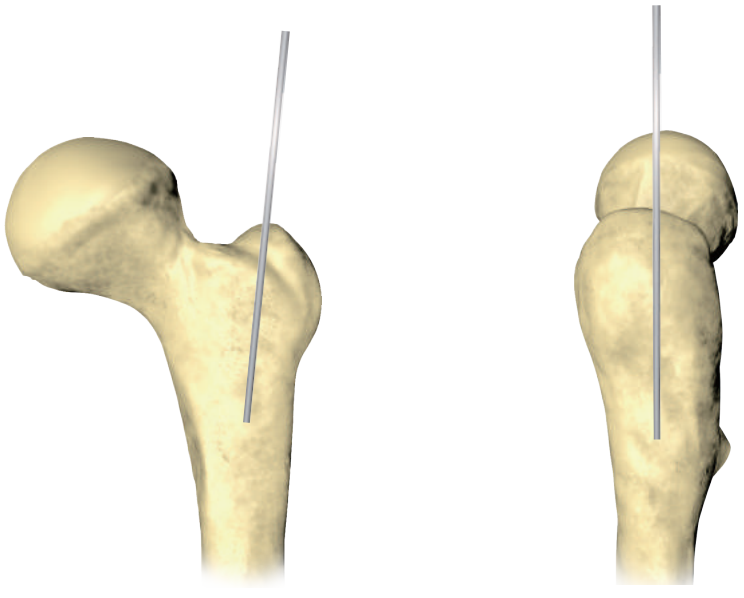
Opening Proximal Femur

Incision and entry point

A longitudinal incision is made proximal to tip of the greater trochanter. Carry the incision through to the fascia and palpate the tip of greater trochanter.

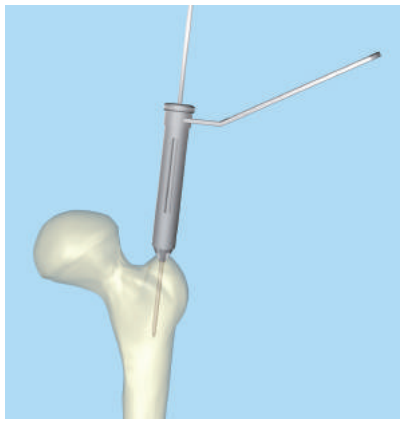
The entry point is located to the tip of the great trochanter, nearly 5 -6 degree from the anatomical axis in the AP and in-line with the intramedullary canal in the lateral.

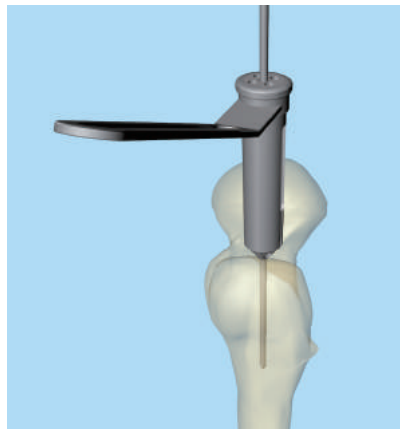




Entry Portal Acquisition

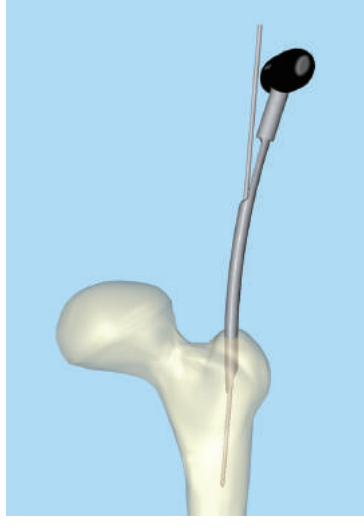
Insert Protection sleeve combination (Protection sleeve, Drill Guide for Guide wire and trocar) through the incision down to bone. Attach a guide pin to power drill or handle. Insert the guide wire into intramedullary canal through the Protection sleeve combination. Confirm Guide pin trocar tip placement in the AP and lateral planes.





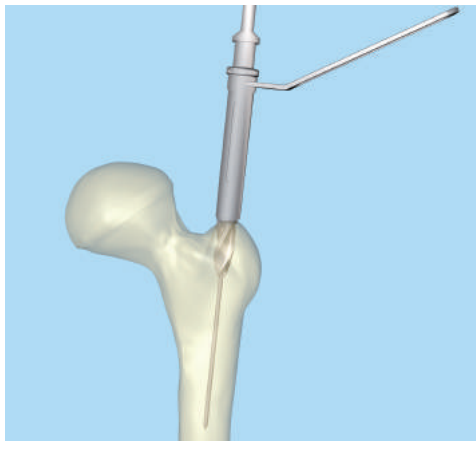
Alternative Option

Place the cannulated awl at the selected starting point and confirm its position in both the A/P and lateral planes on c-arm. Advance the Cannulated Awl through the greater trochanter to the lesser trochanter location.



Open the Femur

After removing the Drill Guide for Guide Wire and trocar, insert the open reamer through the Protection Sleeve over the guide wire, and ream the trochanteric region to open medullary canal until the drill stop on the reamer reaches the protection sleeve.

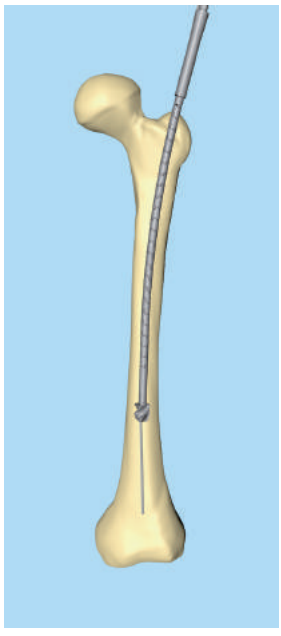


Preparing the Canal

Reaming the medullary canal (Optional)

Insert the reaming rod with Ball tip into the medullary canal to the desired insertion depth.

Beginning with the 8.0mm Reamer Head and Flexible Reamer Shaft, ream the intramedullary canal sequentially in half millimeter increments to a size 1-1.5mm larger than the selected nail diameter.
Ensure Reaming Rod position during reaming by inserting the Reaming Rod pusher into the back of the reamer unit during retraction. Continue to confirm guide rod position throughout reaming. Periodically move the reamer back and forth in the canal to clear debris from the cutting flutes.

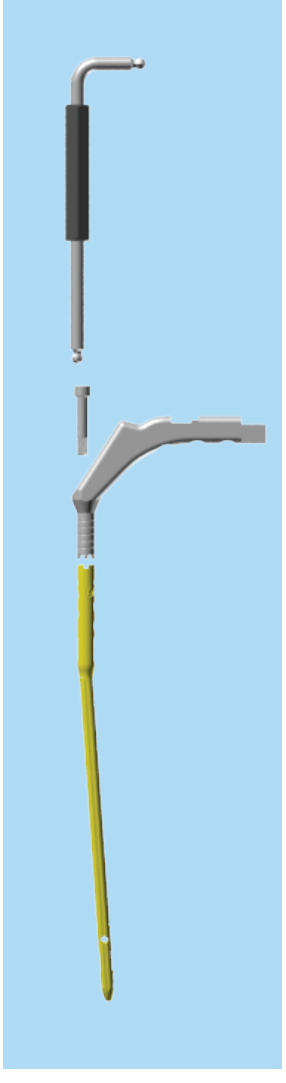


Nail Insertion

Nail assembly

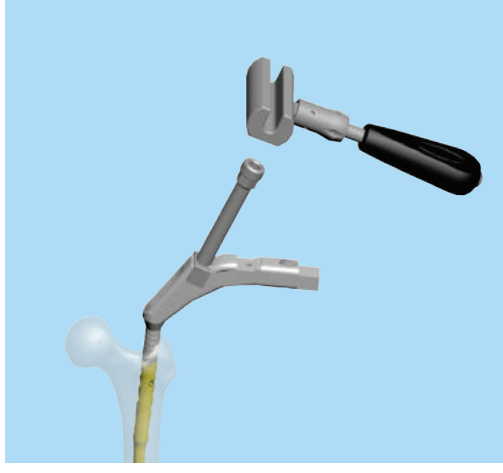
Upon Completion of reaming, the apporiate size nail is ready for insertion. Reaming Rod with Ball tip does not need to be exchanged. Because the Reaming Rod with Ball tip can be penerated into nail or exchange Reaming Rod with Ball tip with Reaming Rod, Straight using tube.

Attach the Assemble Handle to the nail with the Assemble Bolt and tighten with the Assemble Bolt Driver, L type or Assemble bolt, T-type.



Insertion

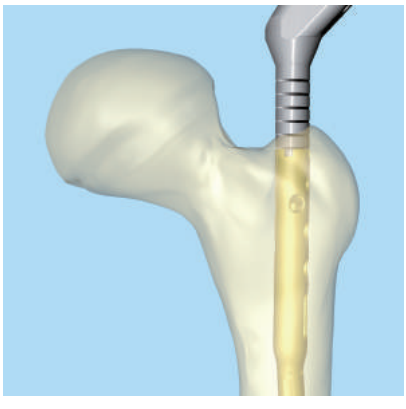
Orient the assemble handle combination in the AP plane and manually insert the nail into the intramedullary canal as far as possible. If necessary, attach the Impactor to the Assemble handle and advance the nail over the Reaming Rod using light blows from the Slotted Mallet. As the distal tip of the nail reaches the isthmus of the canal, rotate the drill guide to the lateral position. Insert the nail to the desired depth. Verify fracture reduction as the nail crosses the fracture site paying close attention to rotation, length, alignment, distraction and shortening.



Insertion Depth

Proximal

Insert the nail until its driving end is at or below the top of the greater trochanter. Each gauge on the insertion barrel represents a 5mm depth interval.



Femoral Locking - Standard Mode

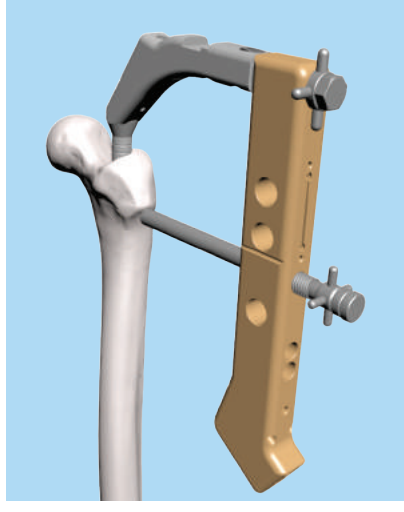
three targeted stadard locking proximal locking options are possible:
- Oblique locking(lesser trochanter endpoint)
- Dynamic locking
- 1 Static locking (L/M)

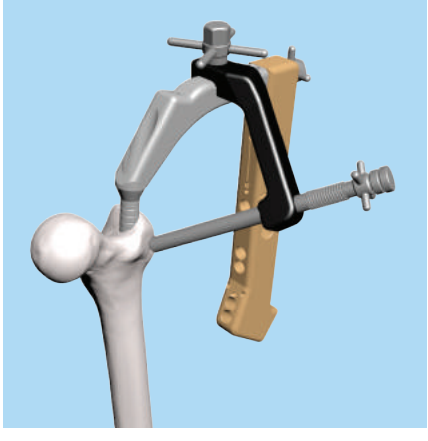
Depending indication, surgeons preference, the locking options will be selected.

Insert Protection Sleeve

Attach the three-part protection sleeve combination for standard locking mode (Protection sleeve, corresponding drill sleeve and trocar) through the desired hole in the Target Guide, make a stab incision and insert the trocar to the bone.

Remove the trocar.



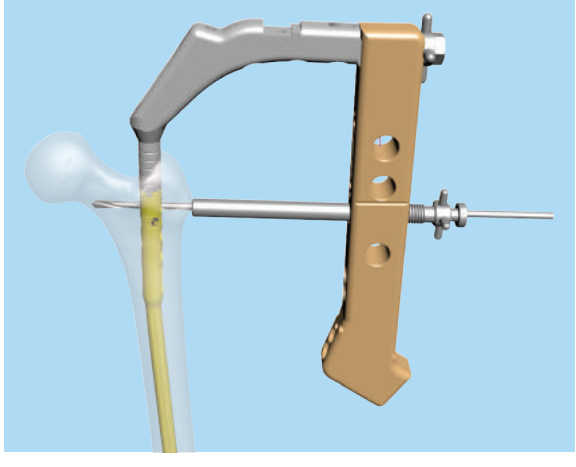


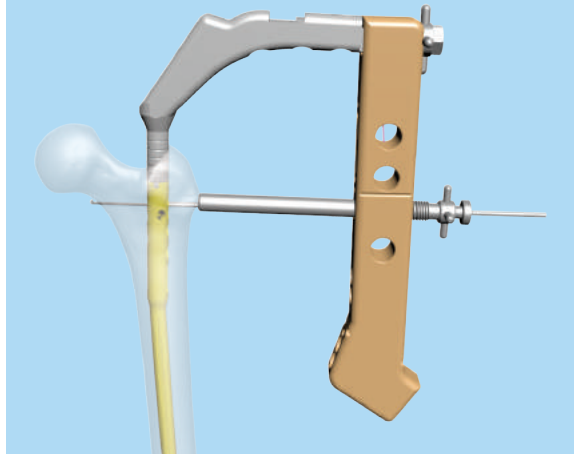
If using the Oblique locking option(lesser trochanter), attach attachable proximal target guide on Assemble handle. And then insert the Protection sleeve combination.

Drill and Determine Locking Screw Length Instruments

Ensure that the drill sleeve is pressed firmly to the lateral cortex. Using the appropriate drill bit (4.3 mm for 5.0mm), drill through both cortices until the tip of the drill bit just penetrates the far cortex.

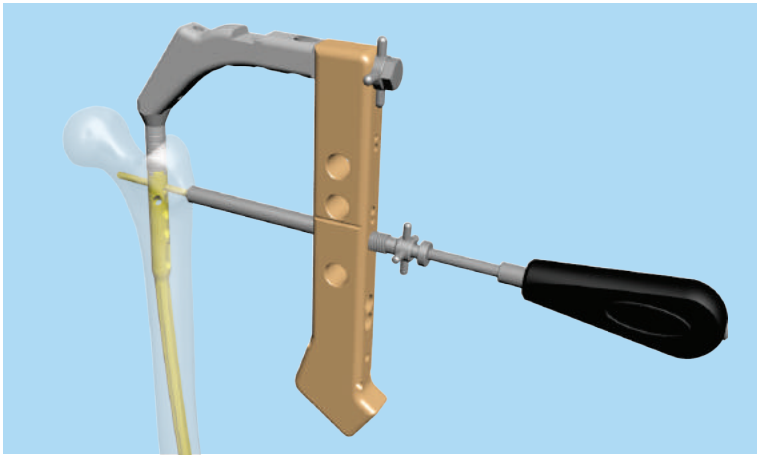
Remove the drill bit, insert depth gauge and measure the screw length.



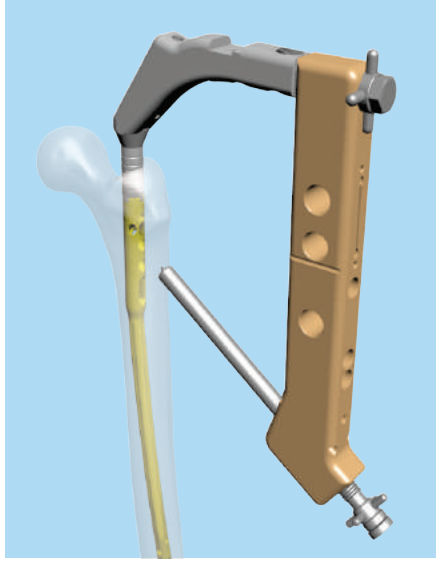


Insert Locking Screw

Insert the appropriate length locking screw through the protection sleeve using the Hex Drive screwdriver. Verify locking screw length under image intensification.The tip of the locking screw should not project more than 2 mm to 4 mm beyond the far cortex.



Femoral Locking - Recon Mode

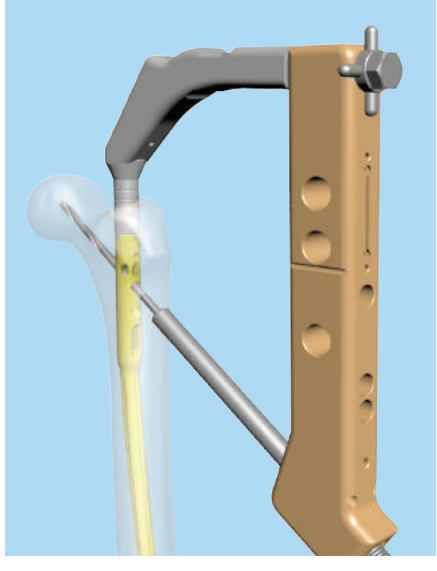


Confirm nail position

In the AP view, adjust the nail insertion depth to ensure that the two recon screws can be placed into the femoral head. Adjust nail position for correct anteversion.

Insert guide wires for recon screws

Insert both protection sleeve, drill sleeve, and trocar through the aiming arm. Make a stab incision and insert the trocars to the bone.

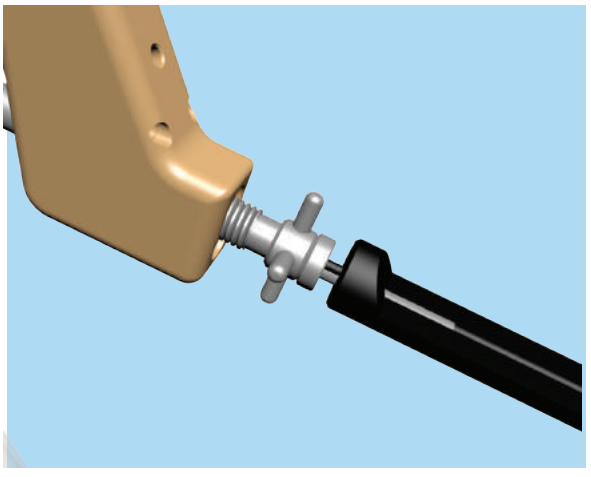


Insert a guide wire, drill tip into the femoral head approximately 5 mm from subchondral bone. Check guide wire placement radiographically in both AP and lateral views.

Insert the second guide wire, drill tip into the femoral head approximately 5mm from subchondral bone. Check the guide wire placement in both AP and lateral views.

Determine Length and Drill for Inferior Recon Screw

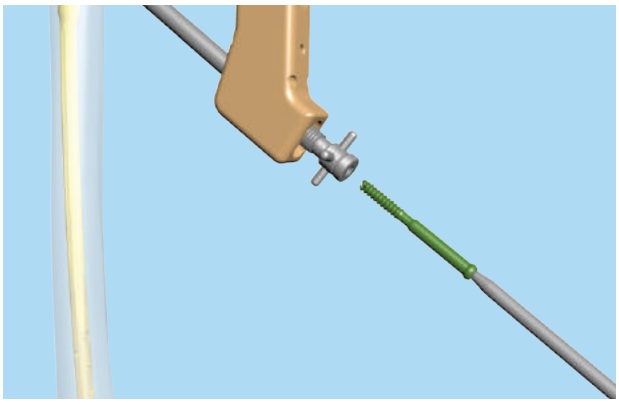
Measure inferior screw. Ensure the protection sleeve is pressed firmly to the lateral cortex. Remove the drill sleeve and insert the direct measuring device over the guide wire into the protection sleeve to the bone. Read the length of the required recon screw
directly on the direct measuring device.
Remove the direct measuring device and the inferior guide wire. Attach the drill stop to the step drill bit for the appropriate length screw.
Guide the step drill bit through the protection sleeve to the bone. Drill to the stop.



Insert Inferior Recon Screw

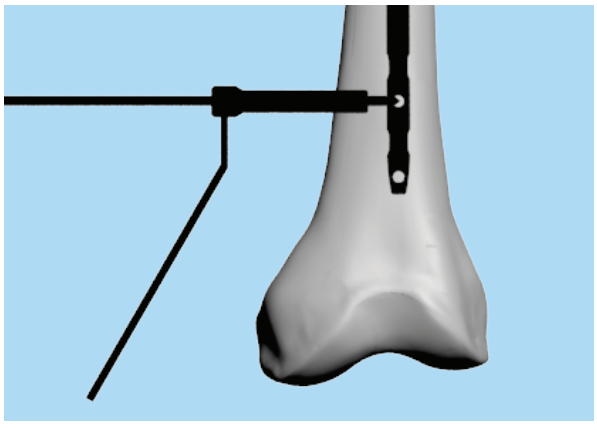
Insert the appropriate recon screw through the protection sleeve into the femoral head, using the long Hex screwdriver. Verify the position of the locking screw under image intensification in both planes.
A groove on the screwdriver indicates when the recon screw is fully inserted.
Repeat steps 3 and 4 for the second, superior recon screw.

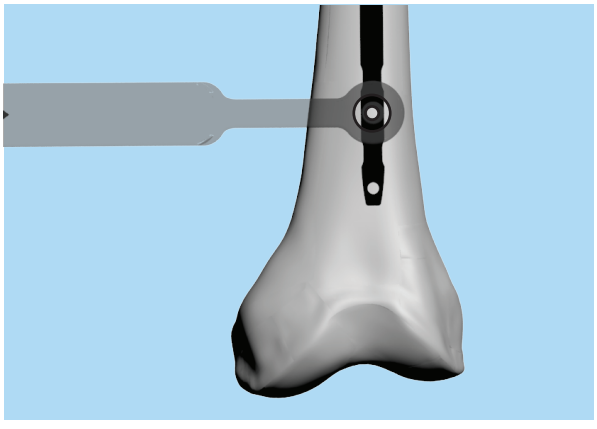
** It can be used with 6.5mm Lag screw or 6.5mm cannulated lag screw.



Distal screw insertion for Nail

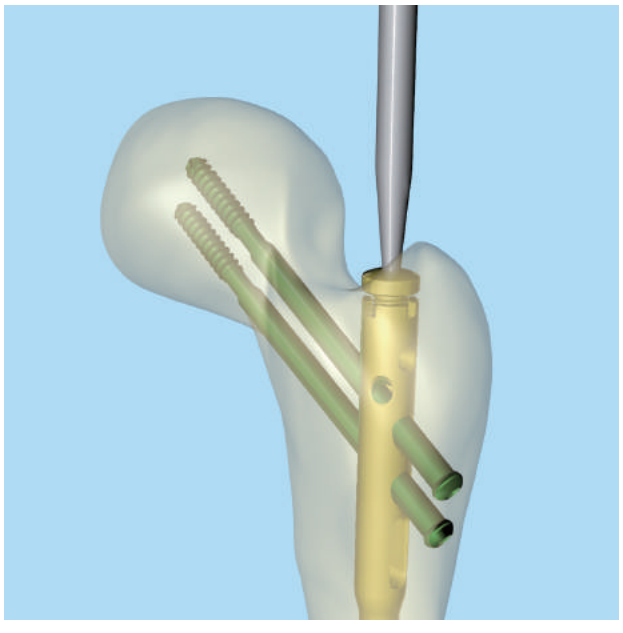
Distal screw insertion on
Femur Nail should be done using freehand technique.
Protection Sleeve for Distal and Drill Sleeve for Distal or Free Handle Drill Guide and
Free Handle Sleeve 4.3mm can be used Drill Bit 4.3mm x 180mm.





Nail Cap Insertion

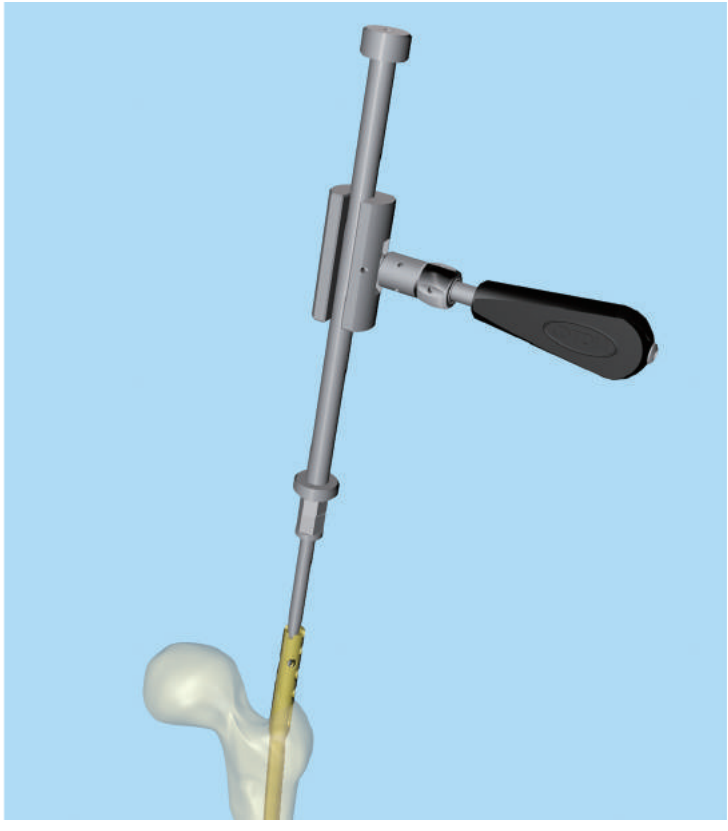
Attach the selected nail cap to cap holding screwdriver. Insert into the top of the nail until tight.



Implant Removal : Optional

Open nail extraction technique

Remove the nail cap if implanted and all but one of the locking screws using the Medium Hexdriver and T-handle. Thread Nail Extractor into the Impactor and introduce the extraction assembly into the top of the nail. Remove the final locking screw(s) and extract the nail with a back-slapping motion using the Slotted Hammer.



Ordering Information - Implant

Femur Reconstruction Nail

Cat No.	Description	Size	
503-29320	Femur Reconstruction Nail, Left	Φ9x320 mm	
503-29340	Femur Reconstruction Nail, Left	Φ9x340 mm	
503-29360	Femur Reconstruction Nail, Left	Φ9x360 mm	
503-29380	Femur Reconstruction Nail, Left	Φ9x380 mm	
503-29400	Femur Reconstruction Nail, Left	Φ9x400 mm	
503-20320	Femur Reconstruction Nail, Left	Φ10x320 mm	
503-20340	Femur Reconstruction Nail, Left	Φ10x340 mm	
503-20360	Femur Reconstruction Nail, Left	Φ10x360 mm	
503-20380	Femur Reconstruction Nail, Left	Φ10x380 mm	
503-20400	Femur Reconstruction Nail, Left	Φ10x400 mm	
503-21320	Femur Reconstruction Nail, Left	Φ11x320 mm	
503-21340	Femur Reconstruction Nail, Left	Φ11x340 mm	
503-21360	Femur Reconstruction Nail, Left	Φ11x360 mm	
503-21380	Femur Reconstruction Nail, Left	Φ11x380 mm	
503-21400	Femur Reconstruction Nail, Left	Φ11x400 mm	
503-22320	Femur Reconstruction Nail, Left	Φ12x320 mm	*Option
503-22340	Femur Reconstruction Nail, Left	Φ12x340 mm	
503-22360	Femur Reconstruction Nail, Left	Φ12x360 mm	
503-22380	Femur Reconstruction Nail, Left	Φ12x380 mm	
503-22400	Femur Reconstruction Nail, Left	Φ12x400 mm	
503-22420	Femur Reconstruction Nail, Left	Φ12x420 mm	
503-23340	Femur Reconstruction Nail, Left	Φ13x340 mm	
503-23360	Femur Reconstruction Nail, Left	Φ13x360 mm	
503-23380	Femur Reconstruction Nail, Left	Φ13x380 mm	
503-23400	Femur Reconstruction Nail, Left	Φ13x400 mm	
503-23420	Femur Reconstruction Nail, Left	Φ13x420 mm	
503-39320	Femur Reconstruction Nail, Right	Φ9x320 mm	
503-39340	Femur Reconstruction Nail, Right	Φ9x340 mm	
503-39360	Femur Reconstruction Nail, Right	Φ9x360 mm	
503-39380	Femur Reconstruction Nail, Right	Φ9x380 mm	
503-39400	Femur Reconstruction Nail, Right	Φ9x400 mm	
503-30320	Femur Reconstruction Nail, Right	Φ10x320 mm	
503-30340	Femur Reconstruction Nail, Right	Φ10x340 mm	
503-30360	Femur Reconstruction Nail, Right	Φ10x360 mm	
503-30380	Femur Reconstruction Nail, Right	Φ10x380 mm	
503-30400	Femur Reconstruction Nail, Right	Φ10x400 mm	
503-31320	Femur Reconstruction Nail, Right	Φ11x320 mm	
503-31340	Femur Reconstruction Nail, Right	Φ11x340 mm	
503-31360	Femur Reconstruction Nail, Right	Φ11x360 mm	
503-31380	Femur Reconstruction Nail, Right	Φ11x380 mm	
503-31400	Femur Reconstruction Nail, Right	Φ11x400 mm	
503-32320	Femur Reconstruction Nail, Right	Φ12x320 mm	*Option
503-32340	Femur Reconstruction Nail, Right	Φ12x340 mm	
503-32360	Femur Reconstruction Nail, Right	Φ12x360 mm	
503-32380	Femur Reconstruction Nail, Right	Φ12x380 mm	
503-32400	Femur Reconstruction Nail, Right	Φ12x400 mm	
503-32420	Femur Reconstruction Nail, Right	Φ12x420 mm	
503-33340	Femur Reconstruction Nail, Right	Φ13x340 mm	
503-33360	Femur Reconstruction Nail, Right	Φ13x360 mm	
503-33380	Femur Reconstruction Nail, Right	Φ13x380 mm	
503-33400	Femur Reconstruction Nail, Right	Φ13x400 mm	
503-33420	Femur Reconstruction Nail, Right	Φ13x420 mm	

End Cap of Femur

Cat No.	Description	Size
530-01000	End Cap for Femur	0 mm
530-01005	End Cap for Femur	5 mm
530-01010	End Cap for Femur	10 mm

Screw

Cat No.	Description	Size
524-65050	6.5mm Lag Screw	50mm
524-65055	6.5mm Lag Screw	55mm
524-65060	6.5mm Lag Screw	60mm
524-65065	6.5mm Lag Screw	65mm
524-65070	6.5mm Lag Screw	70mm
524-65075	6.5mm Lag Screw	75mm
524-65080	6.5mm Lag Screw	80mm
524-65085	6.5mm Lag Screw	85mm
524-65090	6.5mm Lag Screw	90mm
524-65095	6.5mm Lag Screw	95mm
524-65100	6.5mm Lag Screw	100mm
524-65105	6.5mm Lag Screw	105mm
524-65110	6.5mm Lag Screw	110mm

525-65050	6.5mm Cannulated Lag Screw	50mm
525-65055	6.5mm Cannulated Lag Screw	55mm
525-65060	6.5mm Cannulated Lag Screw	60mm
525-65065	6.5mm Cannulated Lag Screw	65mm
525-65070	6.5mm Cannulated Lag Screw	70mm
525-65075	6.5mm Cannulated Lag Screw	75mm
525-65080	6.5mm Cannulated Lag Screw	80mm
525-65085	6.5mm Cannulated Lag Screw	85mm
525-65090	6.5mm Cannulated Lag Screw	90mm
525-65095	6.5mm Cannulated Lag Screw	95mm
525-65100	6.5mm Cannulated Lag Screw	100mm
525-65105	6.5mm Cannulated Lag Screw	105mm
525-65110	6.5mm Cannulated Lag Screw	110mm

520-25026	Nail Locking Screw, Φ5.0mm	26 mm
520-25028	Nail Locking Screw, Φ5.0mm	28 mm
520-25030	Nail Locking Screw, Φ5.0mm	30 mm
520-25032	Nail Locking Screw, Φ5.0mm	32 mm
520-25034	Nail Locking Screw, Φ5.0mm	34 mm
520-25036	Nail Locking Screw, Φ5.0mm	36 mm
520-25038	Nail Locking Screw, Φ5.0mm	38 mm
520-25040	Nail Locking Screw, Φ5.0mm	40 mm
520-25042	Nail Locking Screw, Φ5.0mm	42 mm
520-25044	Nail Locking Screw, Φ5.0mm	44 mm
520-25046	Nail Locking Screw, Φ5.0mm	46 mm
520-25048	Nail Locking Screw, Φ5.0mm	48 mm
520-25050	Nail Locking Screw, Φ5.0mm	50 mm
520-25052	Nail Locking Screw, Φ5.0mm	52 mm
520-25054	Nail Locking Screw, Φ5.0mm	54 mm
520-25056	Nail Locking Screw, Φ5.0mm	56 mm
520-25058	Nail Locking Screw, Φ5.0mm	58 mm
520-25060	Nail Locking Screw, Φ5.0mm	60 mm
520-25062	Nail Locking Screw, Φ5.0mm	62 mm
520-25064	Nail Locking Screw, Φ5.0mm	64 mm
520-25066	Nail Locking Screw, Φ5.0mm	66 mm
520-25068	Nail Locking Screw, Φ5.0mm	68 mm
520-25070	Nail Locking Screw, Φ5.0mm	70 mm
520-25072	Nail Locking Screw, Φ5.0mm	72 mm
520-25074	Nail Locking Screw, Φ5.0mm	74 mm
520-25076	Nail Locking Screw, Φ5.0mm	76 mm
520-25078	Nail Locking Screw, Φ5.0mm	78 mm
520-25080	Nail Locking Screw, Φ5.0mm	80 mm
520-25085	Nail Locking Screw, Φ5.0mm	85 mm
520-25090	Nail Locking Screw, Φ5.0mm	90 mm

Ordering Information - Instrument

910-01001 Protection Sleeve

910-01002 Drill Sleeve for Guide Pin

910-01003 Trocar

910-01004 Open Reamer

910-03038 Primary Awl

910-01012 Assemble Handle for Femur

910-01008 Assemble bolt

910-01013 Proximal Target Guide for Femur

910-01113 Attachable Proximal Target Guide (Left)

910-01114 Attachable Proximal Target Guide (Right)

910-01019 Impact Handle

910-01020 Extract Bolt

910-01120 Extract Bolt with Tip

910-01021 Assemble Bolt Driver (L Ball)

910-01038 Assemble Bolt Driver (T Ball)

910-03060 Wrench

910-01026 Universal Chuck with T-handle

910-03001 Guide Pin (Φ3.0 x 350mm)

910-03030 Assemble / Extract Rod

910-03029 Slotted Mallet

901-01543 Drill Bit (Φ4.3 x 280mm)
901-01343 Drill Bit (Φ4.3 x 180mm)

910-03025 Depth Gauge for Nail Locking Screw

910-01326 Screw Driver, Holding (3.5mm/Long)

910-01043 Protection Sleeve for Femur/Retro, Holding

910-01243 Protection Sleeve for Femur/Retro, Non-Holding

910-01044 Drill Sleeve

910-01045 Troca

910-03051 Guide Pin (Φ3.0x400mm)

910-01047 Step Drill for Recon
910-01147 Step Drill Stopper

910-01143 Protection Sleeve for Recon

910-01144 Drill Sleeve for Recon

910-01245 Trocar for Recon

910-03016 Direct Measuring Device

904-65008 Lag Screw Driver Shaft (Cannulated)

904-65010 Lag Screw Remove Driver, Shaft

904-50017 Quick Coupling Handle for Large

910-01148 End Cap Driver, Flexible

910-05255 End Cap Driver, Rigid

910-01149 Coupling Screw For End Cap Driver , Flexible

910-03226 Screw Driver Shaft, Holding (3.5mm/Small Chuck)

910-03032 Rotation Pin Guide

910-02050 Free Hand Drill Guide

910-02052 Free Hand Drill Sleeve 4.3

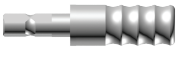
910-90005 Container for Femur Nail Implants
910-90006 Container for Femur Nail Instruments

Ordering Information - Instrument (Optional Items)

901-30343 Pointed Drill Bit, AO Chuck (Φ4.3x160mm)

901-30043 Pointed Drill Bit, AO Chuck (Φ4.3x280mm)

904-40012 Cannulated Quick Chuck Small



Reamer System-Tibia Nail

910-11102 Reaming Rod, Straight Tip

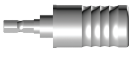
910-11103 Reaming Rod, Ball Tip

910-10028 Start Reamer, Long

910-10000 Flexible Reamer Shaft, Long

910-10080 Reamer Tip (8.0mm)
910-10085 Reamer Tip (8.5mm)
910-10090 Reamer Tip (9.0mm)
910-10095 Reamer Tip (9.5mm)
910-10100 Reamer Tip (10.0mm)
910-10105 Reamer Tip (10.5mm)
910-10110 Reamer Tip (11.0mm)
910-10115 Reamer Tip (11.5mm)
910-10120 Reamer Tip (12.0mm)
910-10125 Reamer Tip (12.5mm)
910-10130 Reamer Tip (13.0mm)
910-10135 Reamer Tip (13.5mm)
910-10140 Reamer Tip (14.0mm)

904-50012 Quich Chuck



910-10009 Rod Pusher

910-10010 Reduction Guide

910-11005 Nail Measuring Plate

910-11004 Alignment Tube

910-90010 Container for Flexible Reamer

TDM

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