Small Fragment System.

Instruments and implants for 2.7 and 3.5 plate fixation.

Technique Guide

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Small Fragment System.

Instruments and implants for 2.7 and 3.5 plate fixation.

The Small Fragment Standard System
The Small Fragment Standard System contains the 2.7, 3.5 and 4.0 implants and related instruments required for standard compression plating.

Features
– Equipment for LC-DCP and DCP plating systems
– Can be upgraded to LCP system
– Cases are organized in general order of use
– Compact case sizes fit most tabletop autoclaves
– Plate case stores a full range of 2.7, 3.5, and 3.5 Broad DCP, LC-DCP or LCP plates
– Includes auxiliary bins for storing additional equipment

The standard system consists of:
– Small Fragment Standard Instrument Set
– Small Fragment Standard Screw Set
– Small Fragment DCP Plate Set (103.513) or Small Fragment LC-DCP Plate Set

The Small Fragment Locking System
The Small Fragment Locking System contains the 2.7 and 3.5 LCP implants and related instruments required for locked plating.

Features
– Dedicated equipment designed for LCP plating
– Locking instruments fit in the Graphic Case for Small Fragment Instrument Set
– All cases are organized in general order of use
– Compact case sizes fit most tabletop autoclaves

The locking system consists of:
– Small Fragment Locking Instrument Set
– Small Fragment Locking Screw Set
– Small Fragment LCP Plate Set


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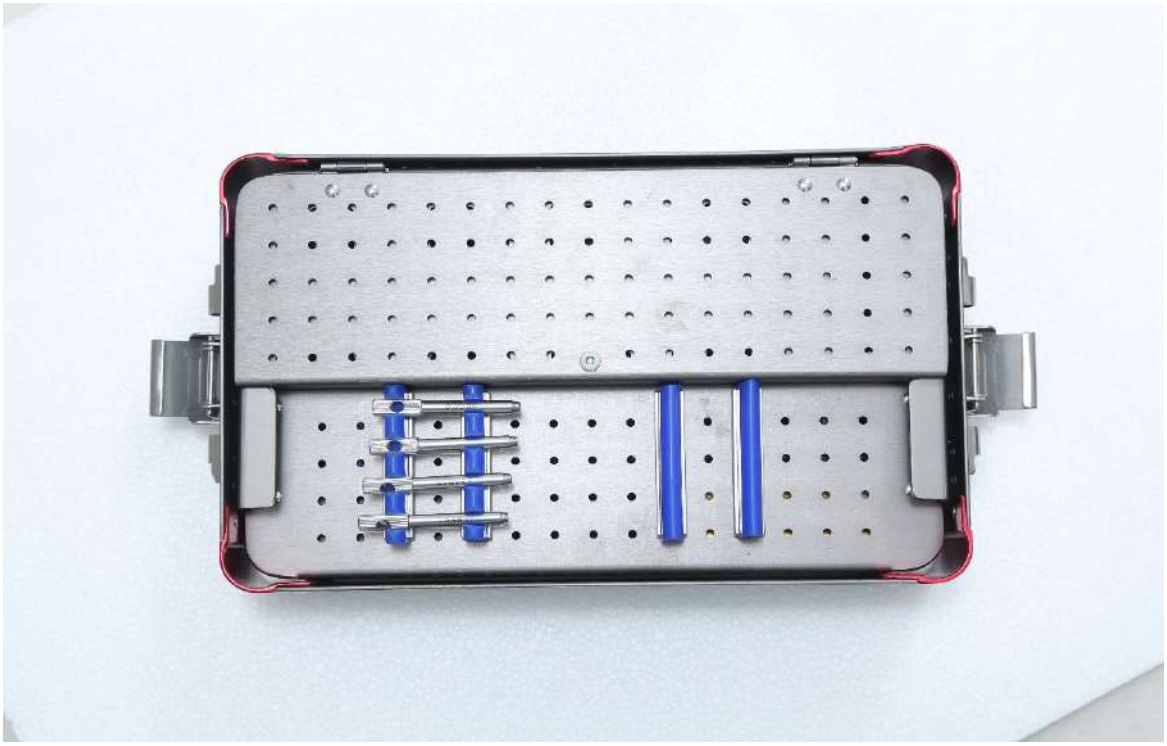



SAMAY
Small Locking Fragment
Instruments set

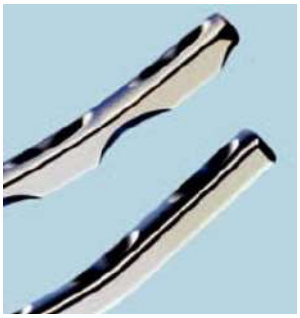
Plates

DCP (Dynamic Compression Plate)

DCP plate hole
– Incorporates an incline in the hole that converts screw compression into plate translation and compression of the bone fracture
– Accepts conventional screws that may be placed in either load or neutral positions, depending on whether inter - fragment compression is desired
– Allows 25° of longitudinal screw angulation and 7° of transverse screw angulation

LC-DCP (Limited-Contact Dynamic Compression Plate) Grooved undersurface
– Provides limited contact between the plate and bone, minimizing the chance for temporary porosis under the plate
– Allows periosteal callus formation at the fracture site

LC-DCP plate hole
– The Dynamic Compression Unit (DCU) hole is symmetrical and provides bidirectional compression
– Allows 40° of longitudinal screw angulation and 7° of transverse screw angulation
– Accepts conventional screws that may be placed in either load or neutral positions, depending on whether inter - fragment compression is desired
– Centrally located hole at one end for metaphyseal fracture repair
– Tapered end for submuscular plate insertion, minimizing tissue trauma

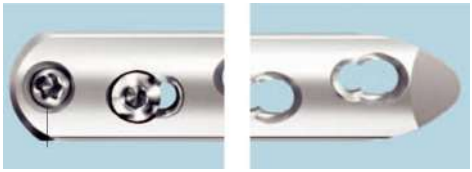


Uniform stiffness
– Allows smooth contouring of the plate to the bone
– Protects the plate from localized high bending stress, because of the even distribution of stresses over a long distance along the plate

LCP (Locking Compression Plate)
– Locking screws create a fixed-angle construct, resulting in angular stability
– Tapered end for submuscular plate insertion, minimizing tissue trauma (1)
– Limited-contact plate design reduces plate-to-bone contact, protecting vascularity
– Centrally located hole at one end for metaphyseal fracture repair

LCP plate holes
– Dynamic Compression Unit (DCU) hole allows 40° of longitudinal screw angulation and 7° of transverse screw angulation
– Combi-holes allow placement of conventional screws on one side or locking screws on the opposite side of each hole

A. Threaded hole section for locking screws
B. Dynamic Compression Unit (DCU) hole section for conventional screws
C. Locking screw in threaded side of plate hole
D. Cortex screw in compression side of plate hole
E. Stacked combi-holes at plate end accepts either cortex, cancellous or locking screws



Screws

Cortex Screws

– For bicortical fixation in diaphyseal bone
– Self-tapping screws are standard in all sets
– Non-self-tapping screws are also available

Cancellous Bone Screws

– For fixation in poor quality or metaphyseal bone
Deeper threads and coarser pitch maximizes the surface area of the threads in contact with the bone, thereby increasing the screw's holding power in softer bone

Locking Screws

– Use with the Locking Compression Plate (LCP)
– Conical, double-lead machine thread on the head locks into the threaded combi-hole or stacked combi-hole in the plate
– Create a fixed-angle construct
– Large core diameter provides improved bending and shear strength
– Hexagonal recess provides improved torque transmission to the screw, while retaining the screw without the use of a holding sleeve

Screw Reference Chart

Thread Diameter	**2.7 mm**	**2.7 mm**	**2.7 mm**	**3.5 mm**	**3.5 mm**	**3.5 mm**	**4.0 mm**
Screw Type	**Cortex**	**Cortex**	**Locking**	**Cortex**	**Cortex**	**Locking**	**Cancellous**
Drill Bit for Threaded Hole	2.0 mm	2.0 mm	2.0 mm	2.5 mm	2.5 mm	2.8 mm	2.5 mm
Tap	self-tapping	self-tapping	self-tapping	self-tapping	self-tapping	self-tapping	4.0 mm
Drive Type	2.5 mm Hexagonal	T8 Hexagonal	T8 Hexagonal	2.5 mm Hexagonal	T15 Hexagonal	T15 Hexagonal	2.5 mm Hexagonal

Screw fixation

Bicortical cortex screw fixation is the traditional method of compressing a plate to the bone. Friction between the plate and bone maintains stability. Therefore, bicortical screws require two cortices of fixation to achieve stability (1).

Locking screws provide stability and load transfer due to the threaded connection between the plate and screw. There is no compression of the plate to the bone (2).

Note: If a combination of a cortex screw and locking screws is used, a cortex screw should be Inserted first to pull the plate to the bone. If a locking screw is used first, care should be taken to ensure that the plate is held securely to the bone to avoid spinning of the plate about the bone.

Warning:

– Samay implants and instruments are manufactured with proprietary processes that produce superior products to those created by conventional manufacturing processes. Though other companies may be able to estimate the Samay general product design, Samay product dimensions are proprietary. The precision design of Samay products is very important for long-term product function and optimal fit between implants.

– Only the finest quality materials are used to manufacture Samay implants. The metals Samay uses have been scientifically proven to be of the best biocompatibility and quality available today.

– With these features and qualities, the mixing of Samay implants with the implants from other companies is not recommended. The overall performance may be compromised due to differences in design, chemical composition, mechanical properties, and quality.

– Given these qualities are trade-secret, no competitor of Samay can make a genuine claim “the same as Samay.” Combining implants from other companies with Samay implants could reduce product performance. Consequently, it is strongly recommended to not mix parts from different manufacturers.

Fixation Principles

Conventional plating using standard screws

Primary loss of reduction
In conventional plating, even though the bone fragments are correctly reduced prior to plate application, fracture disloca-tion will result if the plate contour does not fit the bone (1). In addition, if the lag screw is not seated perpendicular to the fracture line (e.g., spiral fracture of the distal tibia), shear forces will be introduced. These forces may cause loss of reduction.

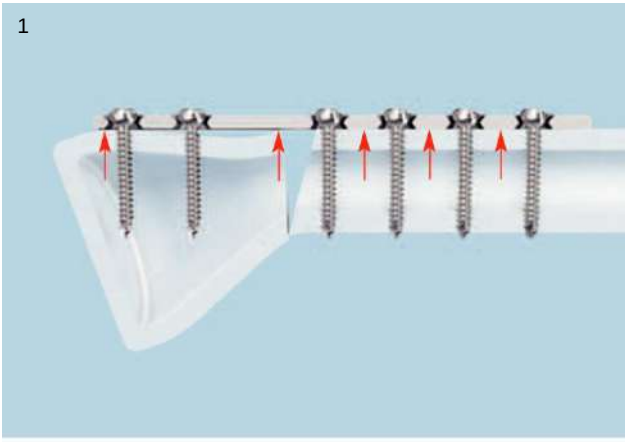
Secondary loss of reduction
Under axial load, postoperative, secondary loss of reduction may occur by toggling of the screws. Since cortex screws do not lock to the plate, the screws cannot oppose the acting force and may loosen, or be pushed axially through the plate holes (2).

Blood supply to the bone
The periosteum is compressed under the plate area, reducing or even interrupting blood supply to the bone (3). This can delay bone healing due to temporary devascularіza-tion underneath the plate.

Poor-quality bone
In poor-quality bone, screws cannot be tightened sufficiently to obtain the compression and friction needed to withstand the loading. This can result in loosening of the screws and loss of stability and reduction.

Standard plating achieves good results in:
– Good-quality bone
– Fractures which are traditionally fixed with lag screws to achieve direct bone healing

1



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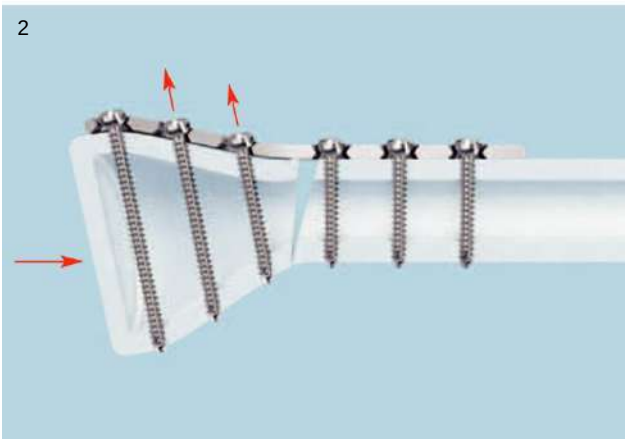

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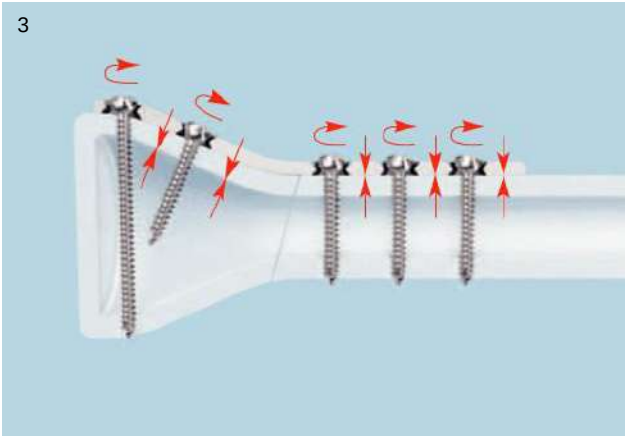

Bridge/locked plating using locking screws
– Screws lock to the plate, forming a fixed-angle construct
– Bone healing is achieved indirectly by callus formation when using locking screws exclusively

Maintenance of primary reduction
Once the locking screws engage the plate, no further tight-ening is possible. Therefore, the implant locks the bone segments in their relative positions regardless of degree of reduction.

Precontouring the plate minimizes the gap between the plate and the bone, but an exact fit is not necessary for implant stability (4). This feature is especially advantageous in minimally or less invasive plating techniques because these techniques do not allow exact contouring of the plate to the bone surface.

Stability under load
By locking the screws to the plate, the axial force is trans - mitted over the length of the plate. The risk of a secondary loss of the intraoperative reduction is reduced (5).

Blood supply to the bone
Locking the screw into the plate does not generate additional compression. Therefore, the periosteum will be protected and the blood supply to the bone preserved (6).

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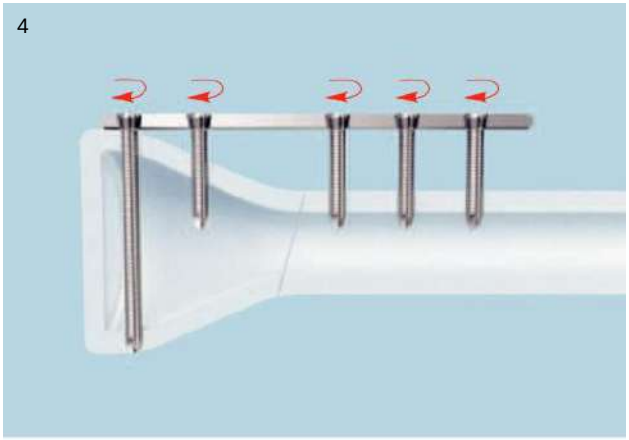

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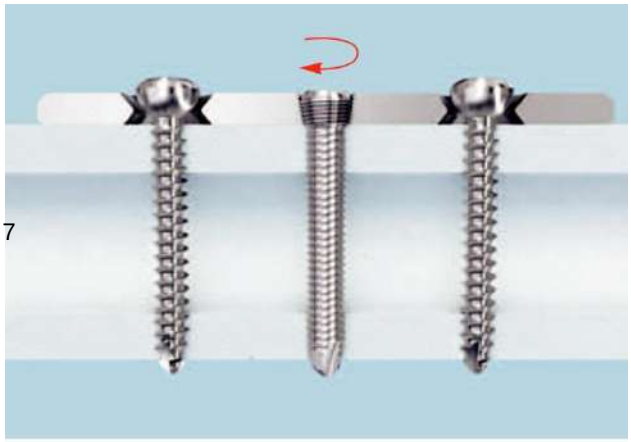
Combined internal fixation
The combination of conventional compression plating and locked plating techniques enhances plate osteo Samay The result is a combination hole or combi-hole that, depending on the indication, allows standard compression plating, locked/bridge plating or a combination of both.

Internal fixation using a combination of locking screws and standard screws

Note: If a combination of standard and locking screws is used, the standard screws should be inserted first to pull the plate to the bone (7).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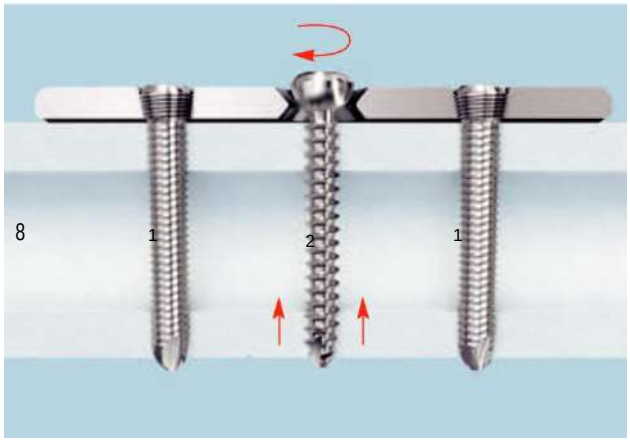
If locking screws (1) have been used to fix a plate to a frag-ment, subsequent insertion of a standard screw (2) in the same fragment without loosening and retightening the lock-ing screws is NOT RECOMMENDED (8).



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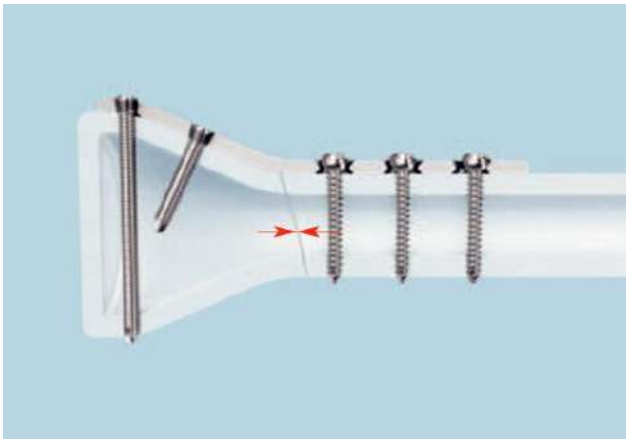
Warning: If a locking screw is used first, care should be taken to ensure that the plate is held securely to the bone to avoid spinning of the plate about the bone.

Dynamic compression
Once the metaphyseal fragment has been fixed with locking screws, the fracture can be dynamically compressed using standard screws in the DCU portion of the combi-hole (9).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Locked and standard plating techniques
– First, use lag screws to anatomically reconstruct the bone surfaces
– The behavior of a locking screw is not the same as that of a lag screw. With the locked plating technique, the implant locks the bone segments in their relative positions regardless of how they are reduced
– A plate used as a locked/bridge plate does not produce any additional compression between the plate and the bone

Preparation

The following techniques apply to any of the Samay plate systems: LCP, LC-DCP and DCP. For this example, a 3.5 LCP plate was selected since it can accommodate both standard and locking screws.

The surgeon should select the appropriate plate system based on indication and experience.

1

Plate selection

Required sets

Small Fragment Instrument Set
Small Fragment Screw Set
Small Fragment LC-DCP Plate Set
Small Fragment LCP Plate Set

The plates are available in various lengths. Complete the preoperative radiographic assessment and plan to determine plate length.

2
Contouring

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Instruments	
	Bending Iron for Plates 2.4 to 3.5, length 145 mm
	Bending Pliers for Plates 4.5, length 250 mm, complete, with Anvils
	Bending Template for LC-DCP 3.5 and DCP 3.5, length 87 mm
	Bending Template for LC-DCP 3.5 and DCP 3.5, length 114 mm
	Bending Template for LC-DCP 3.5 and DCP 3.5, length 153 mm

Use the bending templates to determine plate contour. Use the bending irons or bending pliers to contour the LCP or the LC-DCP plate to the anatomy.

Note: The LCP plate holes have been designed to accept some degree of deformation. When bending the plate, place the bending irons on two consecutive holes. This ensures that the threaded holes will not be distorted. Significant distortion of the locking holes will reduce locking effectiveness. Please refer to the AO Principles of Fracture Management in the Dog and Cat,[1] AO Principles of Fracture Management,[2] and AO Manual of Fracture Management – Internal Fixators.[3]

Reduction and Temporary Plate Placement

3

Reduction and temporary plate placement

Instruments

	Bending Pin for LCP Plates 3.5, with thread, length 100 mm
	Instrument for temporary reduction
	Plate Holding Forceps, with Swivel Foot, size 0
	Holding Forceps with Swivel Foot, for Plates 3.5, speed lock

The plate may be temporarily held in place with standard plate holding forceps or the instrument for temporary reduction.

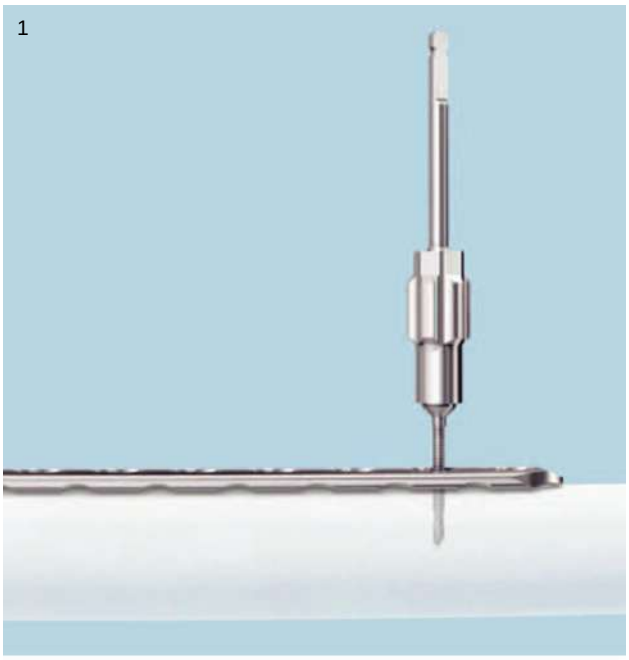
Note: The middle of the plate should be positioned over the fracture site if compression of the fracture fragments is desired.

The instrument for temporary reduction (1) is designed to temporarily hold the plate to the bone through a plate hole. The device is self-drilling and connects with the Samay quick connection for power insertion. Insert into near cortex only. After power insertion, turn the collet clockwise until it pulls the plate securely to the bone.

Note: Care should be taken to avoid inserting this device in a hole that will be needed immediately for plate fixation. However, the device may be removed and a screw inserted through the same plate hole.

A bending pin (2) can also be used as an aid to position the plate, and is particularly useful with minimally invasive plat-ing technique.

1



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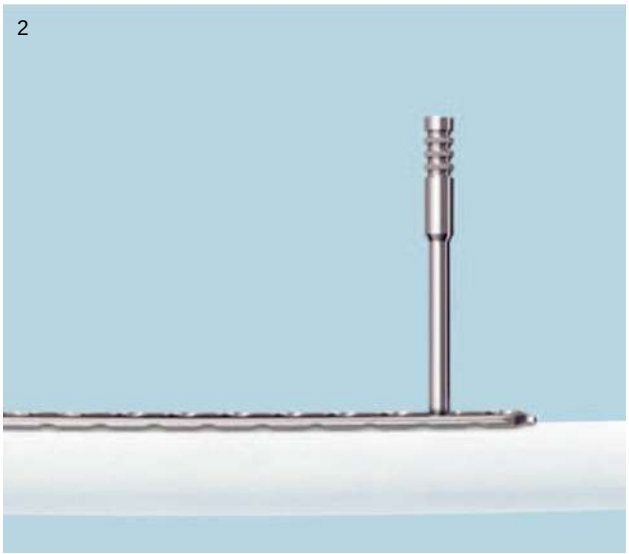


Screw Insertion

4

Screw insertion

Determine whether standard 3.5 mm cortex screws, 4.0 mm cancellous screws or 3.5 mm locking screws will be used for fixation. A combination of all may be used.

Note: If a combination of cortex, cancellous and locking screws is used, a standard screw should be used first to pull the plate to the bone.

Warning: If a locking screw is used first, care should be taken to ensure that the plate is held securely to the bone to avoid spinning of the plate about the bone.

Compression

Insertion of a cortex or cancellous bone screw

Instruments	
	Drill Bit2.5 mm, length 110/85 mm, 2-flute, for Quick Coupling
	Screwdriver, hexagonal, small, with Holding Sleeve
.	Depth Gauge for Screws2.7 to 4.0 mm, measuring range up to 60 mm
.	Universal Drill Guide 3.5

Use the 2.5 mm drill bit through the 3.5 mm universal drill guide to predrill the bone.

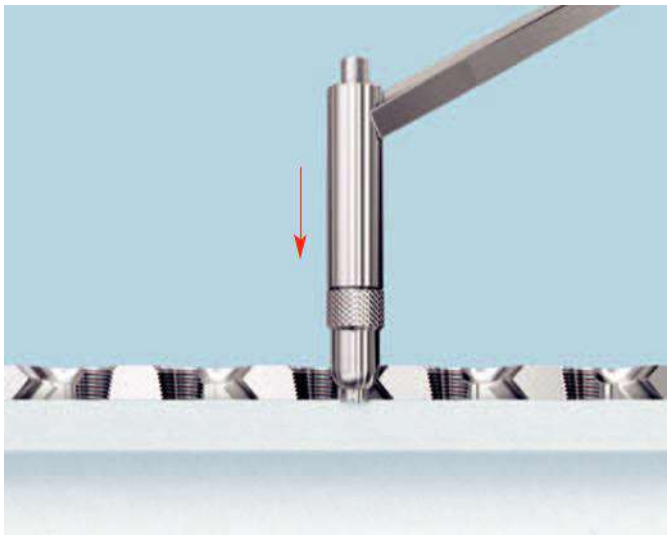
Measure for screw length using the depth gauge.

Select and insert the appropriate 3.5 mm cortex screw using the small hexagonal screwdriver.

Use the 3.5 mm universal drill guide for an eccentric (compression) or neutral (buttress) insertion of cortex screws.

Note: The 3.5 mm LC-DCP drill guide and the 3.5 mm DCP drill guide are not suitable for use with LCP plates.

The universal drill guides are the only drill guides which function in all Samay plate holes. When a cortex or cancel-lous bone screw is used, a universal drill guide should be used to guide the drill bit. If the screw is intended to achieve interfragment compression, the universal drill guide should be placed in the load position, as shown. If the screw is intended to hold the plate, the universal drill guide should be placed in the neutral position.



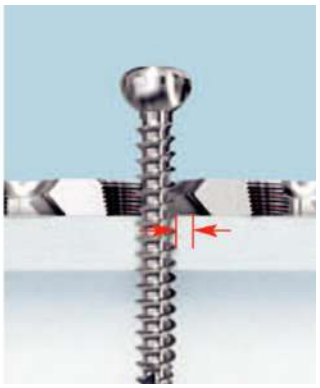
Compression (load) position

Compression is achieved by placing the universal drill guide in the eccentric position, and maintaining the drill guide body above the plate as shown

Neutral position

Neutral position is achieved by placing the universal drill guide in the eccentric position, then compressing the drill guide body into the hole, which will shift the drill guide into the neutral position as shown (2).

Note: For illustrative purposes, a combi-hole has been depicted. The same methodology applies to LC-DCP and DCP holes.



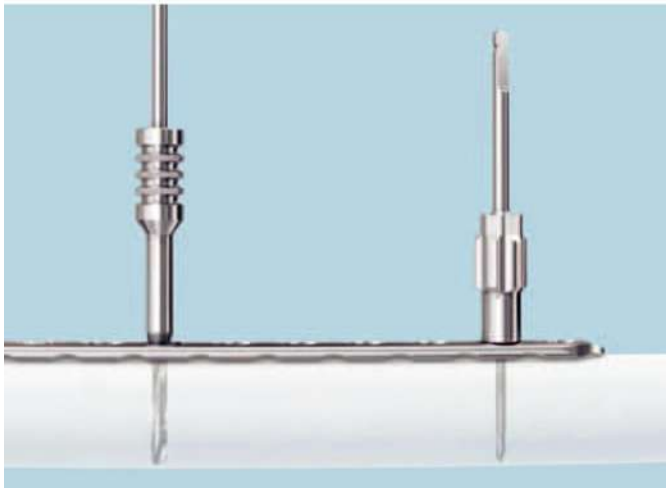
Screw Insertion

Insertion of 3.5 mm locking screws

Instruments	
	Drill Bit2.8 mm, length 165 mm, for AO/ASIF Quick Coupling
	LCP Drill Sleeve 3.5, for Drill Bits2.8 mm
	Screwdriver Hexagonal 3.5, T15
	Screwdriver Shaft Hexagonal 3.5, T15, self-holding, for AO/ASIF Quick Coupling
	Depth Gauge for Screws2.7 to 4.0 mm, measuring range up to 60 mm
	Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling

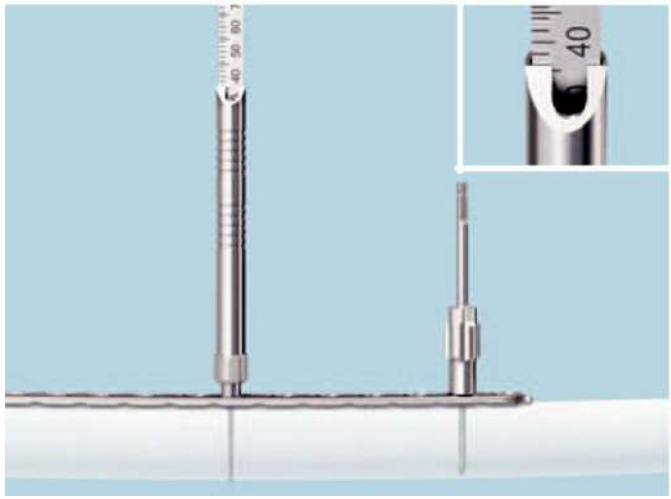
Note: A locking screw cannot be used as a lag screw. Use standard screws when requiring a precise anatomical reduction (e.g., joint surfaces) or interfragmentary compression. Before inserting the first locking screw, perform anatomical reduction and fix the fracture with lag screws, if necessary. After the insertion of locking screws, further anatomical reduction will no longer be possible.

Screw the LCP drill sleeve into an LCP plate hole until fully seated (3).



Note: Since the direction of a locking screw is determined by plate design, final screw position may be verified with a Kirschner wire prior to insertion. This becomes especially important when the plate has been contoured or applied in metaphyseal regions around joint surfaces.

Warning: Do not try to bend the plate using the LCP drill sleeve because damage may occur to the plate hole threads.



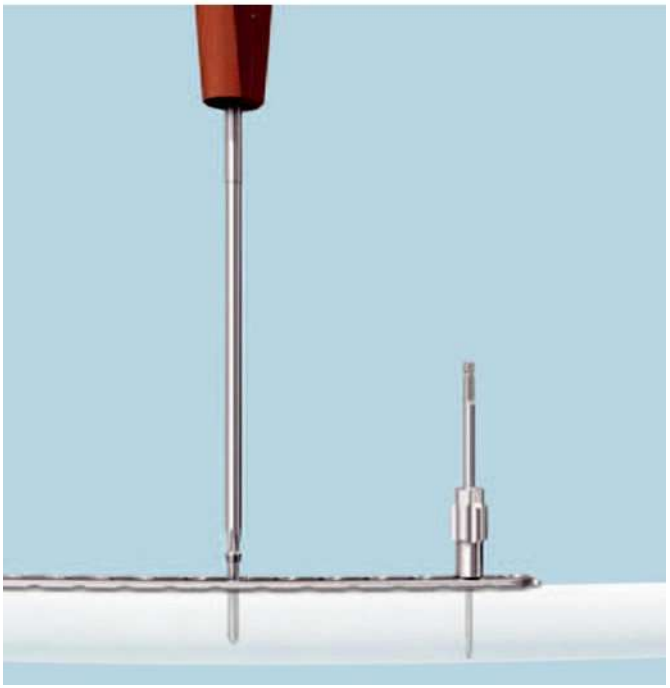
Use the 2.8 mm drill bit to drill to the desired depth (4). Remove the LCP drill sleeve and use the depth gauge to determine screw length (5).

Insert the locking screw under power using the torque limiter and screwdriver shaft (6).

Note: Recheck each locking screw before closing to verify that the screws are securely locked to the plate. Screwheads must be flush with the plate in the locked position before they can be considered fully seated

Warning: Always use a torque limiter when using power to insert locking screws.

Alternative method of locking screw insertion
Use the screwdriver to manually insert the appropriate-ate length locking screw (7). Carefully tighten the locking screw, as excessive force is not necessary to produce effective screw-to-plate locking.



Postoperative Treatment and Implant Removal

Postoperative treatment

Postoperative treatment with locking compression plates does not differ from conventional internal fixation procedures

Implant removal

Sharp Hook, length 155 mm	

When removing a screw, first clear the screw drive mecha-nism (hexagonal or Hexagonal) of all tissue ingrowth using a sharp hook and irrigation. This allows complete engagement of the screwdriver and minimizes the chance of stripping the screw drive mechanism.

When removing locking screws, unlock all screws from the plate; then remove the screws completely from the bone. This prevents simultaneous rotation of the plate when removing the last locking screw

Featured Instruments

Drill Sleeve 2.7, for Aiming Arm

The drill sleeve threads into locking plates for correct alignment of locking screws with plate holes. The drill sleeve centers a drill bit to ensure perpendicular drilling, and permits proper mating of locking screws to the threaded portion of the combi-hole.

LCP Drill Sleeve 3.5, for Drill Bits	2.8 mm

Notes:

– To prevent cross-threading, turn the LCP drill sleeve coun-terclockwise until a slight click is noticed, and then turn it clockwise. If properly aligned, threads should engage within a quarter-turn.

– The LCP drill sleeve can also be used intraoperatively as a reference for visualizing the angle at which the locking screws engage in the bone.

Bending Pin for LCP Plates 3.5,
with thread, length 100 mm
– Facilitates positioning the plate on the bone

Instrument for temporary reduction
– For use with LCP 3.5 plates
– Temporarily compresses the plate to the bone
– Can assist bone fragment reduction to the plate
– Self-drilling, self-tapping 2.5 mm thread
– Samay quick coupling connection

Insert into near cortex only. After power insertion, turn the collet clockwise until it compresses the plate securely to the bone. Take care when inserting this device in a hole that will be needed for plate fixation. After the device is removed, a conventional screw can be placed in the same hole.

Also available

Torque Limiter, 1.5 Nm, for AO/ASIF Quick Coupling
– For use with 3.5 mm locking screws

Torque Limiter, 0.8 Nm, with AO/ASIF Quick Coupling
– For use with 2.7 mm locking screws

A torque limiter is used to ensure the appropriate amount of torque is applied to minimize the risks of a locking screw backing out of the plate.

Note: With titanium implants, this also minimizes the risk of cold welding the screw to the plate. Where steel implants are used, more torque can be applied by hand tightening the screw to ensure it is fully seated in the plate.

Plate Holding Forceps, with Swivel Foot, size 0

Holding Forceps with Swivel Foot, for Plates 3.5, speed lock

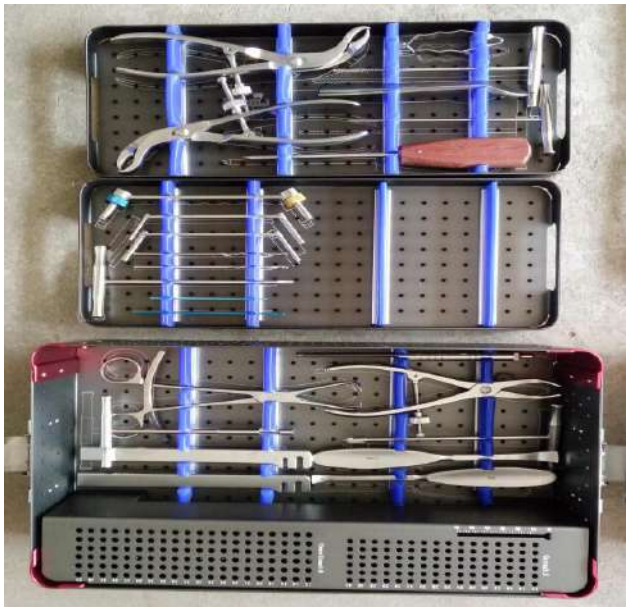
Small Fragment Instrument Set

Graphic Case

Graphic Case for Instrument Set Small Fragments, without Contents

Instruments

Description	Size
Dual-use Drill Guide	2.5mm
Combination Drill Guide	3.0/4.0mm
Combination Drill Guide	2.5/3.5mm
Screw forceps	small
Screw Tap	Cortex 3.5mm
Screw Tap	Cancellous 4.0mm
Drill bit	3.0*115mm
Drill bit	2.5*115mm
Model	10*114mm
Model	10*87mm
Hex screwdriver	SW2.5
Screw Extractor	small
Depth Gauge	60mm
Countersink Drill	small
Anti-slip Screw Extractor	small
Trephining	6mm
Periosteal Elevator	9/12mm
Self-centering Bone Forceps	190mm
Reduction Clamp	170mm
Retractor	15mm
Plate Bender	L/R
Screw tray	
Instrument Case	



Small Fragment Locking Instrument Set

Description	Size
Double drill guide	2.5mm
Screw clamp	
Quick coupling screwdriver	SW2.5
Threaded guide pin	1.5*200mm
Depth Gauge	60mm
T quick coupling handle	
Pin drill sleeve	1.5mm
Pin drill sleeve	2.8mm
Straight quick coupling handle	
Cortex screw tap	3.5mm
Cancellous screw tap	4.0mm
Lift drill	
Locking screw tap	3.5mm
Drill bit	2.5*115mm
Drill bit	2.8*115mm
Torqui handle	1.5N.M
Screw tray and box	

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Quick Reference Guide – Implants

Part Number	Description	Small Fragment Screw Set	Small Fragment Screw Set	Small Fragment Screw Set	Small Fragment LC-DCP Plate Set	Small Fragment LCP Plate Set
SS 106	Cortex Screw2.7 mm, self-tapping, lengths 6 – 30 mm	•		•		
SS 303	Locking Screw 2.7 mm (head LCP 2.4), self-tapping, lengths 12–28 mm		•	•		
SS 107 –	Cortex Screw3.5 mm, self-tapping, lengths 10 – 30 mm	•		•		
SS 304 –	Locking Screw Hexagonal3.5 mm, self-tapping, lengths 12 – 80 mm		•	•		
SS 112 –	Cancellous Bone Screw4.0 mm, fully threaded, lengths 10 – 70 mm	•		•		
SS 132-006	LC-DCP 2.7, 6 holes, length 55 mm				•	
SS 132-008	LC-DCP 2.7, 8 holes, length 73 mm				•	
SS 132-010	LC-DCP 2.7, 10 holes, length 91 mm				•	
SS 132-012	LC-DCP 2.7, 12 holes, length 109 mm				•	
SS 129-006	LC-DCP 3.5, 6 holes, length 80 mm				•	
SS 129-008	LC-DCP 3.5, 8 holes, length 106 mm				•	
SS 129-010	LC-DCP 3.5, 10 holes, length 132 mm				•	
SS 129-012	LC-DCP 3.5, 12 holes, length 158 mm				•	
SS 131-008	LC-DCP 3.5, broad, 8 holes, length 107 mm				•	
SS 131-010	LC-DCP 3.5, broad, 10 holes, length 133 mm				•	
SS 131-012	LC-DCP 3.5, broad, 12 holes, length 159 mm				•	
SS 131-014	LC-DCP 3.5, broad, 14 holes, length 185 mm				•	
SS 310-006	LCP 3.5, 6 holes, length 79 mm					•
SS 310-008	LCP 3.5, 8 holes, length 105 mm					•
SS 310-010	LCP 3.5, 10 holes, length 131 mm					•
SS 310-012	LCP 3.5, 12 holes, length 157 mm					•
SS 312-008	LCP 3.5, broad, 8 holes, length 107 mm					•
SS 312-010	LCP 3.5, broad, 10 holes, length 133 mm					•
SS 312-012	LCP 3.5, broad, 12 holes, length 159 mm					•
SS 312-014	LCP 3.5, broad, 14 holes, length 185 mm					•

Part Number	Description	Small Fragment Standard Screw Set	Small Fragment Locking Screw Set	Small Fragment Screw Set	Small Fragment LC-DCP Plate Set	Small Fragment LCP Plate Set
	Graphic Case for Small Fragment Plate Set, without Contents				•	•
	Rack for Locking Screws2.7 and 3.5 mm, self-tapping, without Contents, with Lid		•	•		
	Rack for Cortex Screws2.7 and 3.5 mm and Cancellous Bone Screws4.0 mm, without Contents, with Lid	•		•		
	Graphic Case for Screw Set Small Fragments, without Contents			•		

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Quick Reference Guide – Instruments

Small Fragment Instrument set

Description	Small Fragment Standard Instrument Set	Small Fragment Locking Instrument Set	Small Fragment Instrument Set
Dual-use Drill Guide	•		•
Combination Drill Guide	•		•
Combination Drill Guide	•		•
Screw forceps	•		•
Screw Tap	•		•
Screw Tap	•		•
Drill bit	•		•
Model	•		•
Hex screwdriver	•		•
Screw Extractor	•		•
Depth Gauge	•		•
Countersink Drill	•		•
Anti-slip Screw Extractor	•		•
Trephining	•		•
Periosteal Elevator	•		•
Self-centering Bone Forceps	•		•
Reduction Clamp	•		•
Retractor	•		•
Plate Bender	•		•
Screw tray	•		•
Instrument Case	•		•

Small Locking Fragment Instrument set

Description	Small Fragment Standard Instrument Set	Small Fragment Locking Instrument Set	Small Fragment Instrument Set
Double drill guide	•		•
Screw clamp	•		•
Quick coupling screwdriver	•		•
Threaded guide pin	•		•
Depth Gauge	•		•
T quick coupling handle	•		•
Pin drill sleeve	•		•
Straight quick coupling handle	•		•
Cortex screw tap	•		•
Cancellous screw tap	•		•
Lift drill	•		•
Locking screw tap	•		•
Drill bit	•		•
Torqui handle	•		•
Screw tray and box	•		•

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Large Fragment set

Surgical Technique

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Table of Contents

Introduction

Large Fragment System llocking plates for the treatment of femur, tibia and humerus shaft fractures. It consists of a Curved Femur Shaft plate and a Straight Narrow Shaft plate.

Straight Narrow Shaft Plate

screw placement (30° cone) with screw locking achieved through the use of locking caps that are threaded into the plate holes. The locking construct allows for improved stability especially in osteopenic bone. Before locking,the screws can act as lag screws and be used for fracture reduction; a benefit which is not offered with standard locking systems.

In the locked mode, the Large Frag-ment Plate acts as an internal fixator without contact between the plate and the bone surface, which may reduce the risk of periosteal blood supply impair-ment. This Non-Contact Bridging concept can also be controlled specifically through the use of 1, 2, or 3mm spacers, which are threaded into the plate holes prior to plate insertion

The surgical technique is based on well-known standard plate osteosynthesis techniques, which give the surgeon tactile feedback regarding bone quality during drilling and tightening of the screws. In addition, with the use of locking caps the screws can be locked and made angularly stable.

The Large Fragment System allows for extensive flexibility in the treatment of simple shaft fractures including peripros-thetic fractures in the shaft. The polyaxial Plate technology, may allow for bicortical screw fixation around the stem of the implanted prosthesis. In this way, the surgeon can achieve better construct stability than with cables with less -damage to the soft tissue. And because of the Non-Contact Bridging concept, the risk to the periosteal blood supply may be reduced.

Additionally, fixation using cables and cable buttons is possible for those cases where bicortical screw fixation cannot be achieved. Both techniques (locking screws and cables) may also be com-bined. Blunt tip unicortical Screws are also available, creating a system which offers comprehensive solutions for these difficult fractures.

System Features

Curved Femur Shaft Plate

Straight Narrow Shaft Plate

Symmetric Design

One plate for left and right long bones due to symmetric design.

Straight Narrow Shaft Plate can either be used for the tibia or humerus. Whereas the Curved Femur Shaft Plate is -specifically designed for the femur.

Compression Slots

Two compression slots allow 1mm of compression each.

K-Wire Holes

Two k-wire holes at each end of the plate allow easier preliminary plate fixation.

Screw Options

Broad Screw Options

Five different Screw types are offered with the Large Fragment System, to allow both bicortical and unicortical fixation.

3.5mm cortical screws are included for additional fixation outside

Specific Instruments for Periprosthetic Fractures

Slightly oversized drill bits and drill guides are offered with the Large Fragment System, to reduce the risk of cracks in the cement mantle when placing screws around a cemented prosthesis.

Bone Spacers (Optional)

Use at least two bone spacers in the diaphyseal area of all Plates, to avoid contact of the plate with the bone surface reducing the risk of periosteal blood supply impairment.

The spacers may also be used if the fracture has been reduced using a cable, to avoid contact between the plate and the cable.

The spacers are available in 1mm, 2mm and 3mm sizes. Insert spacers using the Hexagonal Screwdriver

Note: Insert the bone spacers into the Plate Screw holes before plate insertion-. The spacers are single use only, and they can be removed after locking- the screws.

Screw Inserts (Optional)

To prevent bone ingrowth into empty Screw holes

Blind Screws inserted in a Plate to prevent bone ingrowth

screw insert

use the Blind Screw inserts Insert usi

ng the Hexagonal Screwdriver

Note: Hand tighten only

Indications and Contraindications

Indications

The **Periprosthetic Femur Polyaxial Locking Plate System** is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones, including:

- Periprosthetic fractures
- Comminuted fractures
- Supracondylar fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions

The **Straight Narrow Shaft Plate** is indicated for temporary internal -fixation and stabilization of humeral and tibial shaft fractures and osteotomies, including:

- Periprosthetic fractures
- Comminuted fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions

Contraindications

- All concomitant diseases that may impair the fixation of the implant and/ or the success of the intervention
- Lack of bone substance or poor bone quality which makes stable seating of the implant impossible
- Acute or chronic, local or systemic infections
- Allergy to the implanted materials
- Severe muscular, neural or vascular diseases that endanger the extremities involved
- Loose prosthesis, which requires immediate revision.

Large Fragment Plate Positioning and Screw Fixation

Recommended Plate Positioning

- Ensure that the length of the Curved Femur Shaft Plate or Straight Narrow Shaft Plate allows for screw placement proximal- and distal- of the fracture- zone and if present around the existing prosthesis.

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Recommended Screw Fixation

The Large Fragment System offers three different types of polyaxial locking screws, two of them are designed for bicortical purchase, and one of them is designed for unicortical purchase.

Additionally, 4.5 mm and 5.0mm *MotionLoc* screws are compatible with the Large Fragment System. See surgical-technique for plate/screw compatibility and more specific instructions.

Recommended Screw usage for Curved Femur Shaft Plate:

- Wherever possible, use 5.0mm bicortical Screws.
- In periprosthetic fractures use two bicortical 5.0mm Screws close to the fracture on each side of the fracture.
- For thin cortical bone near the prosthesis,- the 4.5mm Screws may be used.

Recommended Screw usage for Straight Narrow Shaft Plate:

- Use 4.5mm bicortical Screws wherever possible.

Screws – cortical

Screw Type	**Cortical 4.5mm**	**Cancellous Screw 6.5mm**
Outer ⌀	4.5mm	6.5mm
Core ⌀	3.0mm	3.0
Length	10-75mm	20-85mm
REF	SS 109	SS 115
Application	Close to the fracture area, in the shaft area, or in case of a periprosthetic fracture where there is no risk of hitting the prosthesis	In tibia or humerus bone and in case of a periprosthetic fracture away from the fracture area to achieve bicortical fixation around the prosthesis
Drill Bit ⌀	3.2	4.5

Screw Insertion

For All Types of Screws and Locking Caps

- Take care to avoid collision of the screws by choosing the appropriate plate holes and screw lengths.

- Press the Drill Guide into the plate hole perpendicular to the plate and then tilt it in the preferred direction. The drill guide needs to be in constant contact with the bottom ring of the hole. The guide limits the angulation to 15° from the perpendicular axis of the plate or a cone of 30° for placing a locked Screw. Always use the drill guide since it prevents selection of an excessive screw angle and failure of subsequent locking
- Screws may be inserted under power but should be final tightened by hand only.

Note: Screws should not be locked until both sides of the fragment have been fixed.

- Lock the construct, insert and tighten the Locking Caps

) by using the Torque Limiting Screwdriver, 6Nm until a click sound is heard. Make sure the screwdriver is not tilted during its usage. If the driver is tilted, it could damage the hex drive and might complicate the extraction of the implants.

Note: If using the Straight Narrow Shaft Plate for humerus shaft fractures the use of Torque Limiting Screw-driver 4Nm is also acceptable.

In case of periprosthetic fractures do not hit the prosthesis with the tip of the drill, tap or screw

Screw ⌀ 5.0mm

. To insert a 5.0mm Screw use the 4.5mm Drill Guide and drill with the 4.3mm drill bit In case of hard cortical bone or the presence of a cement mantle, tap the
cortex- with the 5.0mm Tap Remove th 4.5mm Drill Guide before using the Tap.

Note: Inserting screws in the presence of a cement mantle can cause cracks, which may cause loosening of the prosthesis.
Overdrilling by using a drill bit of a slightly larger diameter may reduce cracking in the cement mantle during screw insertion. Instead of the 4.5mm drill bit, use the 4.5mm drill bit
and its corresponding drill guide

Unicortical Screw ⌀ 5.0mm

2. Use the Measuring Deviceto determine the appropriate screw length and insert Screw using the Hexagonal Screwdriver or screwdriver shaft

1. To insert a 5.0mm Unicortical use the 4.5mm Drill Guide and drill with the 4.3mm drill bit
In case of hard cortical bone or the presence of cement mantle, tap the cortex with the 5.0mm Tap Remove the 4.5mm Drill Guide before using the Tap.

Note: Inserting screws in the presence of a cement mantle can cause cracks, which may cause loosening of the prosthesis. Overdrilling by using a drill bit of a slightly larger diameter may reduce cracking in the cement mantle during screw insertion. Instead of the 4.5mm drill bit, use the 4.5mm drill bit and its corresponding drill guide

2. Use the Measuring Deviceto determine the appropriate screw length andinsert the Unicortical Screw using the Hexagonal Screwdriver

Note: When using the Measuring Device to measure the length of the Unicortical Screw needed, the device will not hook the far cortex of the bone. Use the screw length measured. Do not use a longer screw.

Cortex Screw ⌀ 4.5mm

1. To insert a 4.5mm Screw
use the 3.2mm
Drill Guide
and drill with the 3.2/4.5mm drill bit

In case of hard cortical bone or the presence of the cement mantle, tap the cortex with the 4.5mm Tap
Remove the 3.2/4.5mm Double Drill Guide before using the Tap.

Note: Inserting screws in the presence of a cement mantle can cause cracks, which may cause loosening of the prosthesis. Overdrilling by using a drill bit of a slightly larger diameter (0.2mm) may reduce cracking in the cement mantle during screw insertion. Instead of the 3.2mm drill bit, use the 3.2mm drill bit and its corresponding
drill guide

2. Use the Measuring Device
to determine the
appropriate screw length and insert the Screw using the Hexagonal Screwdriver or
screwdriver shaft

3. To lock theconstruct, insert the Locking Caps) as described at the beginning of this section.

Locking Screw ⌀ 5.0mm

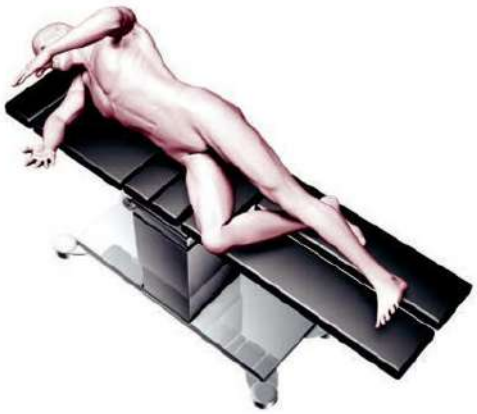
See surgical technique
for
plate/screw compatibility
and more -specific instructions.

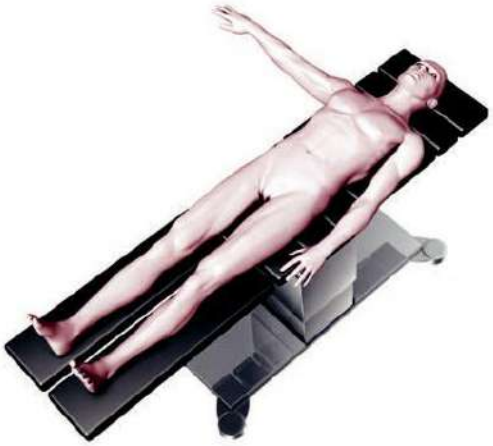
Patient Positioning

Lay the patient in the lateral position or the supine position on a radiolucent table. Support the knee, but allow the leg to move freely. Perform the reduction as necessary.

If intra-op fluoro is to be used, ensure the fluoro machine is not blocked by radioopaque bars of the operating table.

Patient in the lateral position

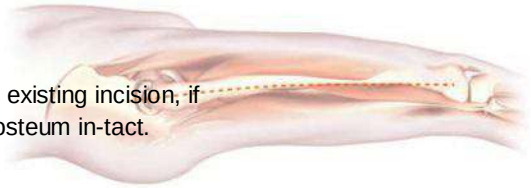




Patient in the supine position

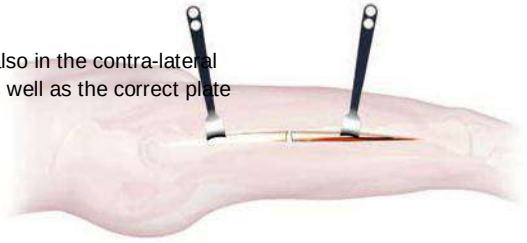
Incision and Intra-operative Planning

Incision



Make the incision using the lateral subvastus approach or incorporate the existing incision, if applicable.Avoid excessive stripping of the soft tissues and keep the periosteum in-tact.

Intra-operative Planning



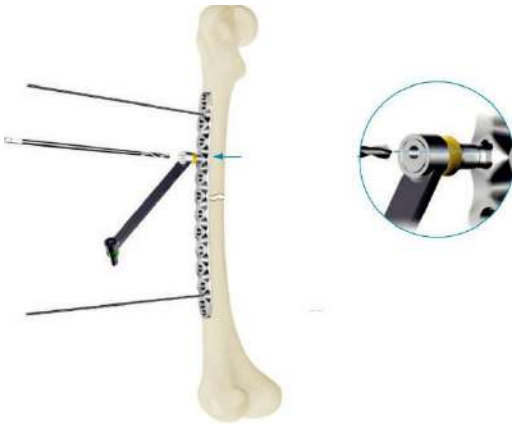
Take complete x-rays of the femur in the A/P and lateral view and if necessary, also in the contra-lateral view, or a CT if osteolysis is present to determine the length of the prosthesis, as well as the correct plate length to be implanted

If desired, the Curved Femur Shaft Plate Provisional can be used to determine the suitable implant length. Provisional is semi -radiolucent and intended to be used in the open technique.

Warning:
Do not implant or bend the provisional.

– the proximal square hole indicates the most proximal Plate hole of the next shorter implant size
– the distal square hole indicates the most distal Plate hole of the next shorter implant size.

Reduction and Preliminary Fixation



Reduce the fracture prior to inserting the plate. Bone fragments may be secured with 2.0mm k-wires or clamps such as pointed reduction forceps. Make sure that preliminary fixation devices do not interfere with the future location of the plate and screws, or with the prosthesis.

Insertion of the Curved Femur Shaft Plate

The following example shows a case without a prosthesis in-situ.
The Curved Femur Shaft Plate is placed on the lateral femur centered over the fracture.
Temporarily fix the plate with two 2.0mm k-wires one proximally and one distally.

Note:

Curved Femur Shaft Plate is anatomically shaped.

If additional contouring is required, use the Bending Press Inserts (SS 1065) and the -corresponding Bending Press

Be aware that bending the plate may decrease its fatigue strength. Furthermore, the locking mechanism of the Screw hole may be damaged and, therefore, may no longer function. Do not use a hole that has been altered by contouring for locking.

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Insertion of the Screws

The Curved Femur Shaft Plate has two compression slots to allow for axial adjustment while positioning the plate, as well as for axial compression.

Note: It is possible to get 1 or 2mm of axial compression with the Curved Femur Shaft Plate. For 2mm of compres-sion,insertthe Screws into the com-pression holes first (like in the example shown in this surgical technique).

For 1mm of compression, insert a Screw into a Plate hole, and then use the compression slot on the opposite side of the fracture. If more compression is needed, use the Articulated Tension Device after only one side of the plate has been fixed. This instrument can be attached to the bone, using a 4.5mm Screw.

Note: Screws should not be locked until

both sides of the fragment have been

fixed.

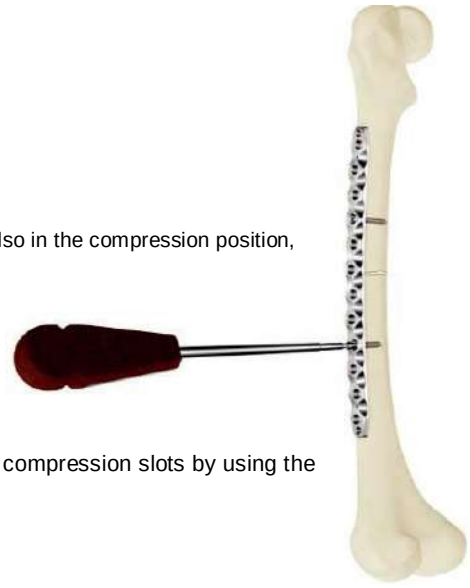
1. For 2.0mm of axial compression, drill the first hole in one of the two compres-sion slots in the compression position using the Compression Drill Guide for 5.0mm Screws and the 4.5mm drill bit Place the compression guide so that the drill hole is at the end of the compression slots farthest from the fracture site.

Partially- insert a 5.0mm Screw into

the compression- slot but do not tighten it.

2.

Partially insert a 5.0mm Screw into the other compression slot, also in the compression position, but do not tighten it.



3. Remove the two 2.0mm k-wires.

To achieve axial compression, tighten the Screws in the two compression slots by using the Hexagonal Screwdriver

4. Insert additional 5.0mm Screws as necessary, first near the fracture site and then proximal/distal to the fracture, ensuring purchase in a minimum of six cortices on each side of the fracture, spaced on the entire length of the plate.

If desired, slightly loosen the 5.0mm

Screws in the two compression slots to

avoid contact between the plate and the

bone.

Straight Narrow Shaft Plate – Surgical Technique

Preoperative Planning and Patient Positioning

Preoperative Planning

Preoperative planning with adequate x-rays and x-ray templates for This allows determination of the proper plate length, and the appropriate type and position of screws, particularly in the presence of prosthesis to prevent any interference with the stem.

In periprosthetic fractures determine which prosthesis has been implanted by studying the x-rays, or using the previous surgeon's operative notes to be prepared in case of revision, and assess the stabili-ty of the prosthesis. If the prosthesis is loose, the surgical plan may change to include revision.

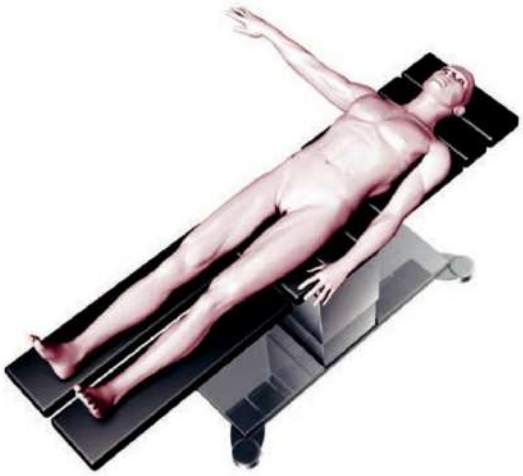
Patient Positioning

Tibia – Lay the patient in the supine
-position on a radiolucent table. Support the
knee, but allow the leg to move freely.
Perform the reduction as necessary.

Humerus – The patient is placed on the operating table in the beachchair posi-tion or supine position. After the patient is in the correct position, the C-arm must be adjusted so as to achieve the widest possible view of the humerus.

If intra-op fluoro is to be used, ensure the fluoro machine is not blocked

by radioo-paque bars of the operating table.



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Incision and Intra-operative Planning

Incision

Tibia: The anterior approach is the stan-dard approach to the tibia, located 1cm lateral to its anterior crest. Take care not to compromise the great saphenous vein and nerve.

Humerus: Plating of humeral shaft frac-tures may be performed through the anterolateral approach.

Intra-operative Planning

Take complete x-rays of the tibia or the humerus respectively in the A/P and lat-eral view and if necessary, also in the contra-lateral view, or a CT if osteolysis is present to determine the length of the prosthesis, as well as the correct plate length to be implanted.

radiolucent and intended to be used in the open technique.

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Reduction and Preliminary Fixation

Reduce the fracture prior to inserting the plate. Bone fragments can be secured with 2.0mm k-wires or clamps such as pointed reduction for-ceps. Make sure that preliminary fixation devices do not interfere with the future location of the plate and screws, or with the prosthesis.

Insertion of the Straight Narrow Shaft Plate

The following example shows a tibia case without a prosthesis in-situ. All steps are also applicable for humerus shaft frac-tures.

The Straight Narrow Shaft Plate is placed on the medial tibia or lateral humerus -centered over the fracture.

Temporarily fix the plate with two 2.0mm k-wires one proximally and one distally

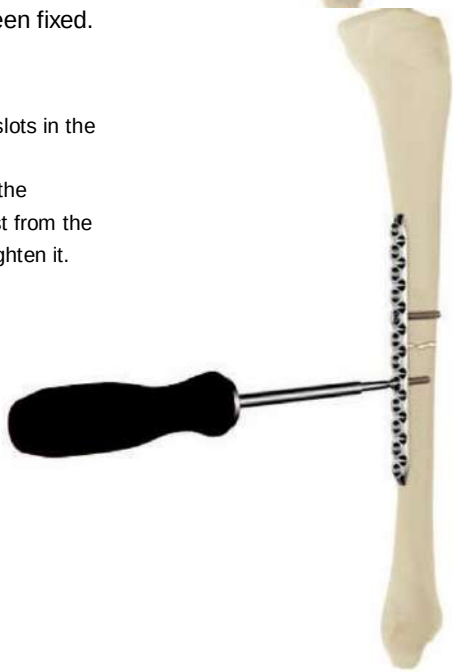
Insertion of the Screws

The Straight Narrow Shaft Plate has two compression slots to allow for axial adjustment while positioning the plate, as well as for axial compression.

Note: If using the compression slots inser-tion of 4.5mm Screws is required.

Note: It is possible to get 1 or 2mm of axial compression with the Straight Narrow Shaft Plate. For 2mm of compres-sion, insert the Screws into the com-pression holes first (like in the example shown in this surgical technique). For 1mm of compression, insert a Screw into a Plate hole, and then use the compression slot on the opposite side of the fracture.

Note: Screws should not be locked until both sides of the fragment have been fixed.



1. For 2.0mm of axial compression, drill the first hole in one of the two compression slots in the compression position
using the Compression Drill Guide for 4.5mm Screws and the 3.2mm drill bit Place the compression guide so that the drill hole is at the end of the compression slots farthest from the fracture site. Partial-ly insert a 4.5mm Screw into the com-pression slot but do not tighten it.

2. Partially insert a 4.5mm Screw into the other compression slot, also in the compression position, but do not tighten it.

Remove the two 2.0mm k-wires. To achieve axial compression,

tighten the Screws in the two compression slots by using the Hexagonal Screwdriver

4. Insert additional 4.5mm Screws as necessary, first near the fracture site and then proximal/distal to the fracture, ensur-ing purchase in a minimum of six cortices on each side of the fracture, spaced on the entire length of the plate.

If desired, slightly loosen the 4.5mm Screws in the two compression slots to avoid contact between the plate and the bone.

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Tips and Tricks for the Large Fragment System used in periprosthetic fractures

Drilling into Cement Mantle

In patients with cemented prostheses, the insertion of screws may occur in the presence of a cement mantle. This can cause cracks, which may cause loosening of the prosthesis. Be careful not to hit the prosthesis when tapping, drilling and inserting screws.

Tips, which may Mitigate this Risk

- Use a lower speed for drilling into the cement mantle to prevent overheating and avoid cement melting
- Use a higher feed rate (increased drill force)
- Use only new sharp drill bits. Change drills frequently and do not use worn ones
- drill bits are available:
  - 3.5mm drill bit
  - 4.5mm drill bit
- Use taps
- Overdrilling by using drill bits of a slightly larger diameter (0.2mm) may reduce cracking in the cement mantle during screw insertion. In the Large Fragment set a 3.5mm drill bit can be used in place of the 3.2mm drill bit, and a 4.5mm drill bit can be used in place of the 4.5mm drill bit. These drill bits are available together with their corresponding drill guides.

Note: Overdrilling the cement mantle by 0.2mm does reduce pull out strength by about 20%. However, within the cement mantle pull out

Drilling into Cortical Bone

In order to go around the stem of the prosthesis and achieve bicortical fixation, it may be necessary to drill completely into cortical bone, which can lead to heat necrosis of the bone.

Warning: Drilling and inserting screws into the outer edge of the cortical bone may also lead to cortical fracture.

Tips, which may Mitigate these Risks

- Use only new sharp drill bits. Change drills frequently and do not use worn ones
- Pull the drill bit out often and clean its flutes
- Use extensive irrigating fluid (i.e. saline water) directed at the point of penetration of the cortex
- Use taps

Metal Abrasion Wear

Metal abrasion wear due to contact between screws, plates, prostheses, cable buttons, and cables may occur.

Tip, which may Mitigate this Risk

Use only products compatible with the Large Fragment System, which are described in this surgical technique

Post-Operative Treatment Implant Removal

Post-operative treatment with locking plates does not differ from conventional internal fixation procedures. If there is concern about stability, consider using additional external fixation devices and/ or a cast/brace. Early range of motion exercises of the involved joints may also be beneficial. However, it is the responsibility of the surgeon to determine the most suitable post-operative care depending on each patient's health condition.

To remove the Large Fragment Plates, first remove all locking caps. Then, loosen all the them (this prevents rotation of the

bone plate when removing the last screw). Finally, completely remove all

Note: Make sure that the tip of the

Hexagonal Screwdriver is correctly placed in the hex drive of the locking caps and/ or Screws. Failure to do so could damage the hex drive and complicate the extraction of the implant.

Removal Tip

In case of difficulties while loosening the

Screws, tighten the screws slightly

before loosening them.

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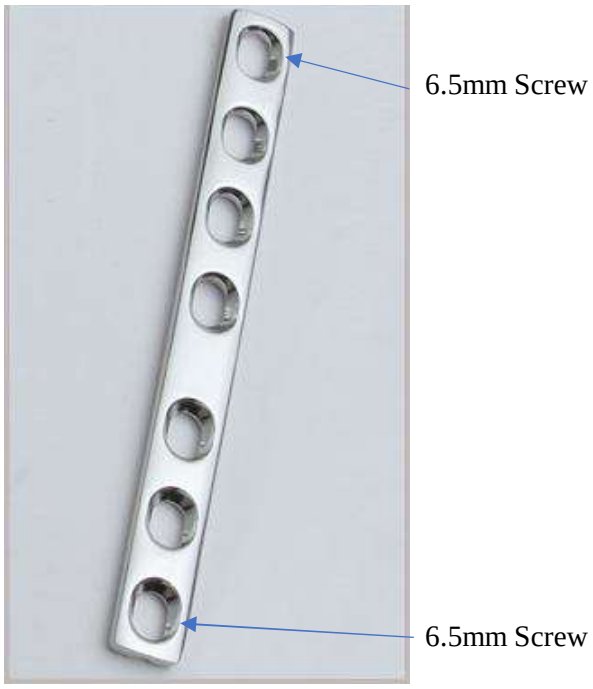
Product Information – Implants

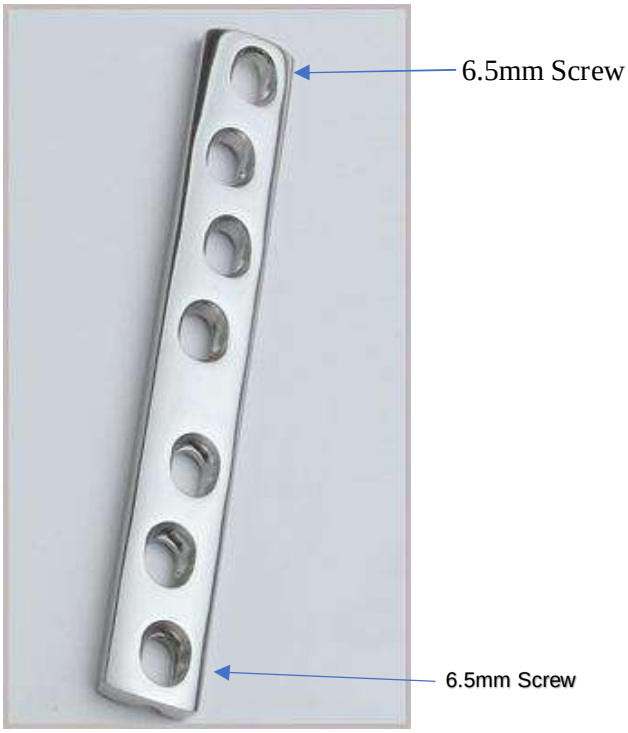
4.5 mm Narrow Compression (DCP) Plates

SS 127	4.5 mm Narrow Compression (DCP) Plates
SS 127-004	04 Hole
SS 127-005	05 Hole
SS 127-006	06 Hole
SS 127-007	07 Hole
SS 127-008	08 Hole
SS 127-009	09 Hole
SS 127-010	10 Hole
SS 127-011	11 Hole
SS 127-012	12 Hole
SS 127-013	13 Hole
SS 127-014	14 Hole
SS 127-015	15 Hole
SS 127-016	16 Hole
SS 127-017	17 Hole
SS 127-018	18 Hole
SS 127-019	19 Hole
SS 127-020	20 Hole



4.5 mm Broad Compression (DCP) Plates

SS 128	4.5 mm Broad Compression (DCP) Plates
SS 128-005	05 Hole
SS 128-006	06 Hole
SS 128-007	07 Hole
SS 128-008	08 Hole
SS 128-009	09 Hole
SS 128-010	10 Hole
SS 128-011	11 Hole
SS 128-012	12 Hole
SS 128-013	13 Hole
SS 128-014	14 Hole
SS 128-015	15 Hole
SS 128-016	16 Hole
SS 128-017	17 Hole
SS 128-018	18 Hole
SS 128-019	19 Hole
SS 128-020	20 Hole
SS 128-021	21 Hole
SS 128-022	22 Hole



SAMAY Surgical

Materials: Products are made from Titanium & Stainless Steel

SS 130	4.5 mm Narrow Compression (LC-DCP) Plates
SS 130-004	04 Hole
SS 130-005	05 Hole
SS 130-006	06 Hole
SS 130-007	07 Hole
SS 130-008	08 Hole
SS 130-009	09 Hole
SS 130-010	10 Hole
SS 130-011	11 Hole
SS 130-012	12 Hole
SS 130-013	13 Hole
SS 130-014	14 Hole
SS 130-015	15 Hole
SS 130-016	16 Hole
SS 130-017	17 Hole
SS 130-018	18 Hole
SS 130-019	19 Hole
SS 130-020	20 Hole

SS 131	4.5 mm Broad Compression (LC-DCP) Plates
SS 131-005	05 Hole
SS 131-006	06 Hole
SS 131-007	07 Hole
SS 131-008	08 Hole
SS 131-009	09 Hole
SS 131-010	10 Hole
SS 131-011	11 Hole
SS 131-012	12 Hole
SS 131-013	13 Hole
SS 131-014	14 Hole
SS 131-015	15 Hole
SS 131-016	16 Hole
SS 131-017	17 Hole
SS 131-018	18 Hole
SS 131-019	19 Hole
SS 131-020	20 Hole
SS 131-021	21 Hole
SS 131-022	22 Hole

SAMAY Surgical

SS 312	4.5 mm Broad Locking Plates
SS 312-004	04 Hole
SS 312-005	05 Hole
SS 312-006	06 Hole
SS 312-007	07 Hole
SS 312-008	08 Hole
SS 312-009	09 Hole
SS 312-010	10 Hole
SS 312-011	11 Hole
SS 312-012	12 Hole
SS 312-013	13 Hole
SS 312-014	14 Hole
SS 312-015	15 Hole
SS 312-016	16 Hole
SS 312-017	17 Hole
SS 312-018	18 Hole
SS 312-019	19 Hole
SS 312-020	20 Hole
SS 312-021	21 Hole
SS 312-022	22 Hole

SS 311	4.5 mm Narrow Locking Plates
SS 311-004	04 Hole
SS 311-005	05 Hole
SS 311-006	06 Hole
SS 311-007	07 Hole
SS 311-008	08 Hole
SS 311-009	09 Hole
SS 311-010	10 Hole
SS 311-011	11 Hole
SS 311-012	12 Hole
SS 311-013	13 Hole
SS 311-014	14 Hole
SS 311-015	15 Hole
SS 311-016	16 Hole
SS 311-017	17 Hole
SS 311-018	18 Hole
SS 311-019	19 Hole
SS 311-020	20 Hole

Materials: Products are made from Titanium & Stainless Steel

SAMAY Surgical

SS 305	5.0 mm Locking Screw
SS 305-016	16.0 mm
SS 305-018	18.0 mm
SS 305-020	20.0 mm
SS 305-022	22.0 mm
SS 305-024	24.0 mm
SS 305-026	26.0 mm
SS 305-028	28.0 mm
SS 305-030	30.0 mm
SS 305-032	32.0 mm
SS 305-034	34.0 mm
SS 305-036	36.0 mm
SS 305-038	38.0 mm
SS 305-040	40.0 mm
SS 305-042	42.0 mm
SS 305-044	44.0 mm
SS 305-046	46.0 mm
SS 305-048	48.0 mm
SS 305-050	50.0 mm
SS 305-052	52.0 mm
SS 305-054	54.0 mm
SS 305-056	56.0 mm
SS 305-058	58.0 mm
SS 305-060	60.0 mm
SS 305-062	62.0 mm
SS 305-064	64.0 mm
SS 305-066	66.0 mm
SS 305-068	68.0 mm
SS 305-070	70.0 mm
SS 305-075	75.0 mm
SS 305-080	80.0 mm
SS 305-085	85.0 mm
SS 305-090	90.0 mm

Materials: Products are made from Titanium & Stainless Steel

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SS 109	TT 109	4.5 mm CORTEX SCREW (Pitch 1.75)
SS 109-010	TT 109-010	10.0 mm
SS 109-012	TT 109-012	12.0 mm
SS 109-014	TT109-014	14.0 mm
SS 109-016	TT 109-016	16.0 mm
SS 109-018	TT 109-018	18.0 mm
SS 109-020	TT 109-020	20.0 mm
SS 109-022	TT109-022	22.0 mm
SS 109-024	TT 109-024	24.0 mm
SS 109-026	TT 109-026	26.0 mm
SS 109-028	TT 109-028	28.0 mm
SS 109-030	TT 109-030	30.0 mm
SS 109-032	TT 109-032	32.0 mm
SS 109-034	TT 109-034	34.0 mm
SS 109-036	TT109-036	36.0 mm
SS 109-038	TT 109-038	38.0 mm
SS 109-040	TT 109-040	40.0 mm
SS 109-042	TT 109-042	42.0 mm
SS 109-044	TT109-044	44.0 mm
SS 109-046	TT 109-046	46.0 mm
SS 109-048	TT 109-048	48.0 mm
SS 109-050	TT109-050	50.0 mm
SS 109-052	TT 109-052	52.0 mm
SS 109-054	TT 109-054	54.0 mm
SS 109-056	TT 109-056	56.0 mm
SS 109-058	TT109-058	58.0 mm
SS 109-060	TT109-060	60.0 mm
SS 109-062	TT 109-062	62.0 mm
SS 109-064	TT 109-064	64.0 mm
SS 109-066	TT 109-066	66.0 mm
SS 109-068	TT 109-068	68.0 mm
SS 109-070	TT 109-070	70.0 mm
SS 109-075	TT 109-075	75.0 mm
		(Self Tapping)

Materials: Products are made from Titanium & Stainless Steel

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SS 115	6.5 mm CANCELLOUS SCREW FULLY THREADED
SS 115-020	20.0 mm
SS 115-025	25.0 mm
SS 115-030	30.0 mm
SS 115-035	35.0 mm
SS 115-040	40.0 mm
SS 115-045	45.0 mm
SS 115-050	50.0 mm
SS 115-055	55.0 mm
SS 115-060	60.0 mm
SS 115-065	65.0 mm
SS 115-070	70.0 mm
SS 115-075	75.0 mm
SS 115-080	80.0 mm
SS 115-085	85.0 mm
SS 115-090	90.0 mm
SS 115-095	95.0 mm
SS 115-100	100.0 mm
SS 115-105	105.0 mm
SS 115-110	110.0 mm
SS 115-115	115.0 mm
SS 115-120	120.0 mm

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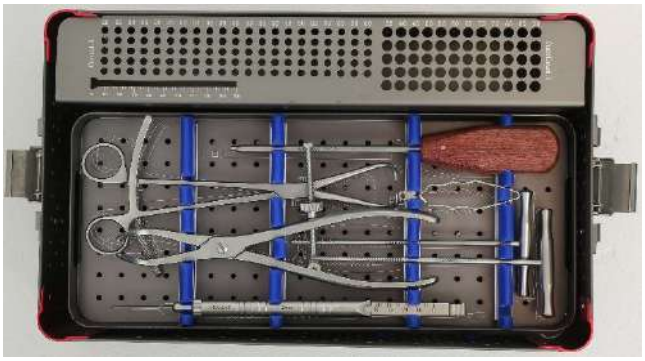

SAMAY Surgical

Large Fragments Sets		
Drill Bit	3.2*115mm	2
Drill Bit	4.5*115mm	2
Countersink Drill	Large	1
Cortex screw tap	4.5mm	1
Cancellous screw tap	6.5mm	2
Screw forceps	Large	3
Dual-use Drill Guide	3.2mm	1
Double drill guide	4.5/6.5mm	1
Double drill guide	3.2/4.5mm	1
Model	12*120mm	1
Model	12*155mm	1
Model	12*212mm	1
Depth Gauge	90mm	1
Anti-slip Screw Extractor	Large	1
Trephining	8mm	1
Hex screwdriver	3.5mm	1
Reduction forceps with points	210mm	1
Reduction forceps	225mm large	1
Self-centering Bone Forceps	260mm	2
Periosteal Elevator	12/15mm	2
Retractor	18/42mm	2
Plate Bender	L/R	2
Screw tray		1
Instrument Case		1

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Large Locking Instrument Set		
Double drill guide	3.2mm	1
Screw clamp		1
Pin drill sleeve	2.0mm	1
Drill bit	4.3mm	2
Drill bit	3.2mm	2
Threaded guide pin	2.0*250mm	2
Depth Gauge	90mm	1
T quick coupling handle		1
Pin drill sleeve	4.3mm	1
Cortex screw tap	4.5mm	1
Cancellous screw tap	6.5mm	1
Lift drill		1
Locking screw tap	5.0mm	1
Quick coupling screwdriver	SW3.5	1
Torque handle	4.0N.M	1
Screw tray and box		1

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Omega3 System
Compression Hip Screw

Hip Fractures

Operative Technique

- Hip Fracture
- Axially Stable Locking Option

Contents

Introduction

The Omega3 Compression Hip Screw is a unique and innovative system reflecting the long experience of Stryker Osteosynthesis in the treatment of hip fractures.

This modular system offers the surgeon a wide choice of slimlined hip plates combined with a unique option of cephalic implants and state of the art instrumentation.

The system provides a simple and easy-to-use solution for surgeons facing hip fractures.

The Omega3 Hip Fracture System denotes the new locking technique for the hip plate shaft holes.
Only the Omega3 Hip Plates offer the possibility to apply 5.0mm Locking Inserts and Locking Screws in the plate diaphysis as well as standard 4.5mm Cortical Screws, 6.5mm Cancellous Screws and Cannulated Screws.

To apply Locking Inserts and Locking Screws to the Omega3 Hip Plate, the appropriate locking instrumentation is available in the optional locking instrument set.

All Omega2 instruments are compatible with the Omega

3 Hip Plates

Types of screws compatible with Omega Plates

Screw type	OmegaPlus	Omega2	Omega3
Ø4.5mm Cortical Screws	4	4	4
Ø6.5mm Cancellous Screws	4	4	4
Ø6.5mm III Cannulated Screws	4	4	4
Ø5.0mm Locking Inserts and Screws	6	6	4

Potential Features & Benefits

Omega3
Low Profile Hip Plate

- Available in both Standard Barrel (38mm) and Short Barrel (25mm) styles and a full range of sizes and angles.
- Hip Plate barrel accepts the Omega Plus Lag Screws or Twin Hook.
- In addition to 4.5mm Cortical Screws, all sideplate holes accept 6.5mm Cancellous Screws or 6.5mm Cannulated Screws for additional stabilization.
- The Hip Plate allows for 5.0mm Locking Inserts used in combination with 5.0mm Locking Screws for angular stable fixation. Bi-directional shaft holes increase the fixed angled construct. Innovative Locking Screws are guided into the plates, thus reducing potential for cross-threading and coldwelding.
- Tapered plate allows for easier slide in when used in minimal invasive technique with short incision.

Locking Insert

Locking Screw

Omega3
Lag Screw Options

13mm Standard Lag Screw

- Leading edge of the cutting thread engages quickly, with or without tapping, and provides tactile control during final positioning.

15mm Super Lag Screw

- Provide excellent resistance to migration in case of osteoporotic bone.

State of the Art Instrumentation

Accurate angle guides:

- Radiolucency (Fig. 1) of the angle guide body to precisely position the instrument, and therefore the Guide Pin.
- Multiple guide pin holes (Fig. 3) for accurate placement of the Guide Pin without need to move the instrument.
- Variable Angle Guide (Fig. 4) with “freehand” technique option.
- Stiff CoCr Ø2.8mm Guide Pin (Fig. 2) for reduced deflection. Available also with quick coupling for increased interface between the power tool and the Guide Pin.
- Compatibility with the Locking Plate System.
- Layout of the trays sequenced according to the surgical technique.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Relative Indications &•Contraindications

Relative Indications

The Omega3 System is indicated for fractures of the proximal femur which may include:

• **Trochanteric fractures and subtrochanteric fractures**

• **Intracapsular and basal neck fractures**

Note: When treating subtrochanteric fractures with Omega3 Hip Plates, the length of the Hip Plate has to be chosen according to the fracture situation. An intramedullary device like the Gamma3 Long Nail may be an option for the treatment of subtrochanteric fractures.

Note: When using the Omega3 Lag Screw System, if there is rotational instability, it is recommended that an **6.5mm Cannulated Screw** or

Pin be added to stabilize the fracture. Please refer to page 15 (Fig. 21).

Relative Contraindications

The surgeon's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

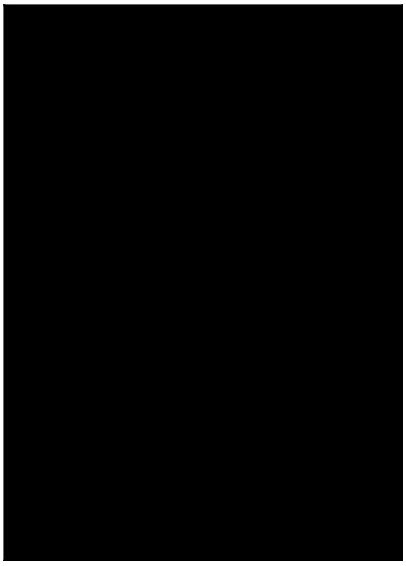
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An 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.

Detailed information are included in the instructions for use being attached to and shipped with every implant.

See package insert for a complete list of potential adverse effects and contraindications. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Caution: Bone Screws are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Preoperative Planning



Review the frontal and lateral X-Rays of the pelvis and injured femur prior to surgery to assess fracture stability, bone quality, as well as neck-shaft angle and to estimate plate length required.

Tip: Use templates (Fig. 5) praeoperatively to plan plate angle, plate length, barrel length, and Lag Screw length.

The Lag Screw should be centered in the head on both anterior-posterior and lateral views, within 10 millimeters of subchondral bone. Application of the template to an X-Ray of the uninvolved hip may help simulate reduction of the fractured hip.

Fig. 5

Preoperative X-Ray Templates for Omega3 System

Description:
Omega3 X-Ray Template Lag Screw 130 deg.
Omega3 X-Ray Template Lag Screw 135 deg.
Omega3 X-Ray Template Lag Screw 140 deg.
Omega3 X-Ray Template Lag Screw 145 deg.
Omega3 X-Ray Template Lag Screw 150 deg.
Omega3 X-Ray Template Supracondylar Plate 95 deg.
Omega3 X-Ray Template Folder, empty. (**Note:** for the storage of the above mentioned X-Ray templates)

Patient Positioning

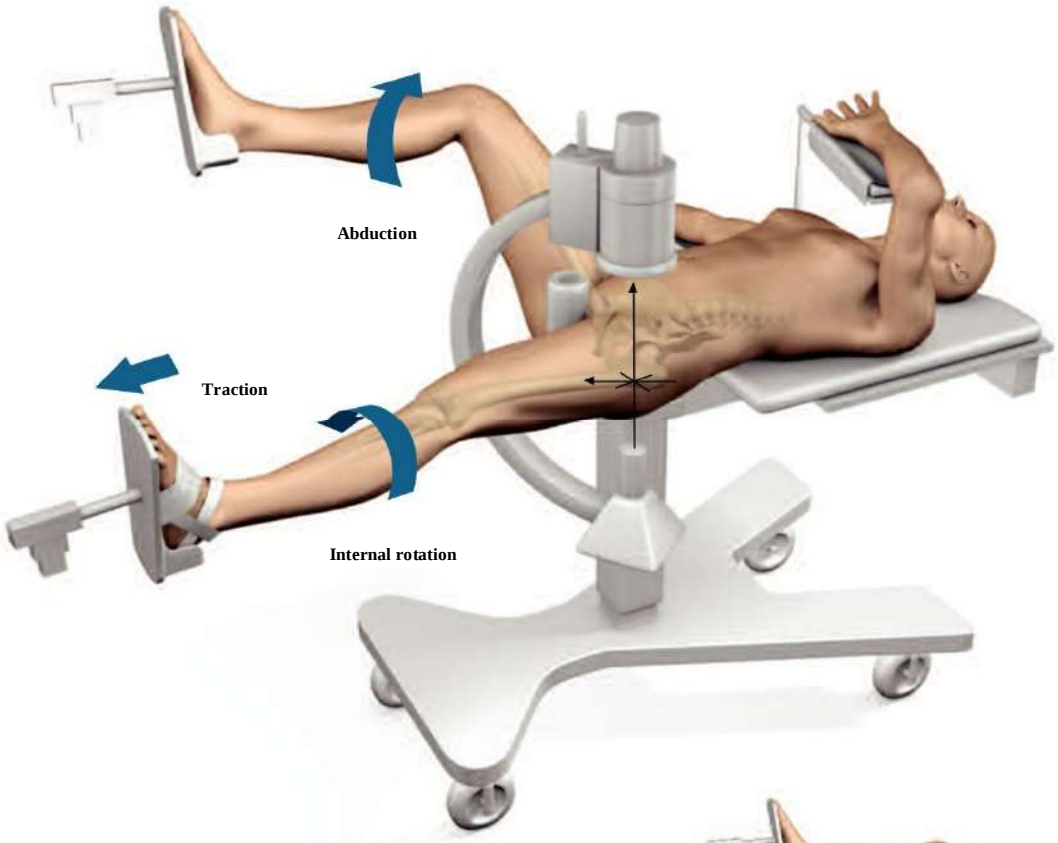
The patient is placed supine on the fracture table with the hip extended, adducted and slightly rotated inwards, until the patella is in a position parallel to the ground.

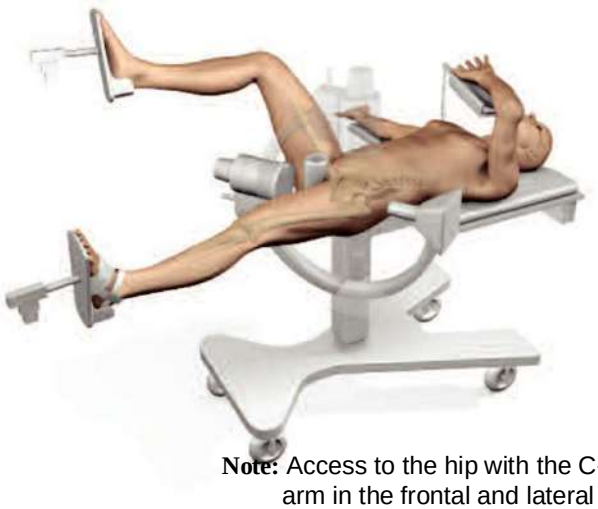
Satisfactory access to the hip with the C-arm in the frontal and lateral planes is verified.

The fracture is reduced as anatomically as possible by longitudinal traction, adduction and internal rotation on a fracture table.

Any inferior "sagging" at the fracture site seen on the lateral view should be corrected by elevating the fracture from posterior, prior to fixation.

In unstable fractures, Guide Pins can be placed in order to stabilize the reduced fragments.





Note: Access to the hip with the C-arm in the frontal and lateral planes is essential for the success of the system.

Skin Incision

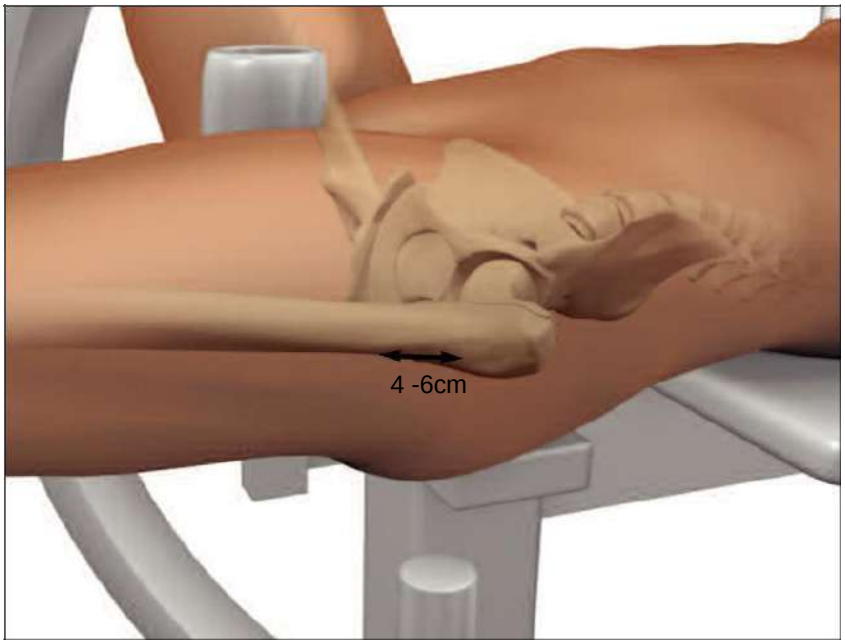


Fig. 6

A 4 to 6 centimetre incision is made, starting at the tip of the greater trochanter and continuing straight distally. Depending on the indication, choice of plate length or minimal invasive technique the skin incision may be chosen shorter or longer (Fig. 6).

The incision is continued through the subcutaneous tissue and tensor fascia lata in line with the skin incision.

Guide Pin Insertion

Orientation and placement of the Guide Pin is one of the most critical steps in this procedure.

By utilizing one or more of the following visual landmarks, correct positioning of the Guide Pin can be achieved.

With the Guide Pin placed at 135° angle, the pin crosses the lateral cortex at the level of the lesser trochanter (Fig. 7 & 8); at the insertion of the gluteus maximus at the posterolateral edge of the femur; or two fingerbreadths (2.5 to 3.5cm) below the crest of the greater trochanter at the origin of the vastus lateralis.

For each 5° change in hip plate angle, the Guide Pin insertion point will be moved approximately 5mm distally (for increased angle) or proximally (for decreased angle).

The Fixed Angle Guide corresponds to the barrel plate angle. Angles of 130°, 140°, 145° or 150° may be guided using the Variable Angle Guide.

In the following description of the operative technique the most common used 135° CCD is shown in the procedure.

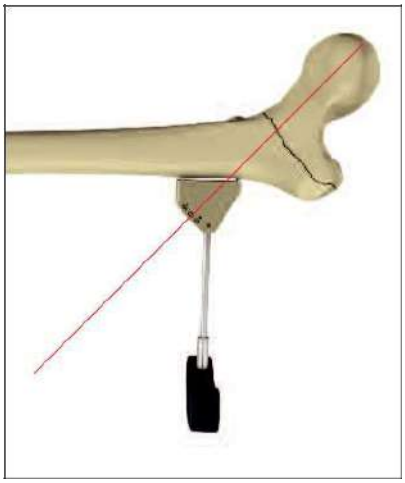


Fig. 7 Fixed Angle Guide for Guide Pin Placement

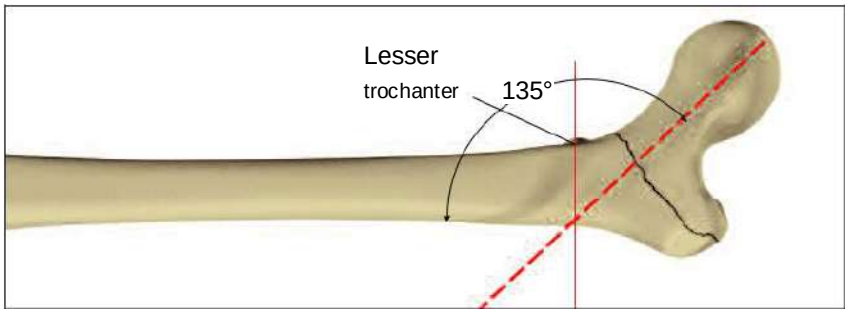


Fig. 8

A Variable Angle Guide (Fig. 9) in conjunction with an T-Handle can be used to insert the guide pin at 130°, 135°, 140°, 145° and 150°.

Note: The Angle Guides are radiolucent (Fig. 10) to help the correct positioning of the Angle Guide and the Guide Pin under image intensifier (helpful when a reduced skin incision is performed and direct visibility of the site is therefore reduced).

Note: Be sure to verify that the set angle is not changed when the Variable Angle Guide is touching soft tissue. This may occur when used in minimal invasive approach the incision is made too small.

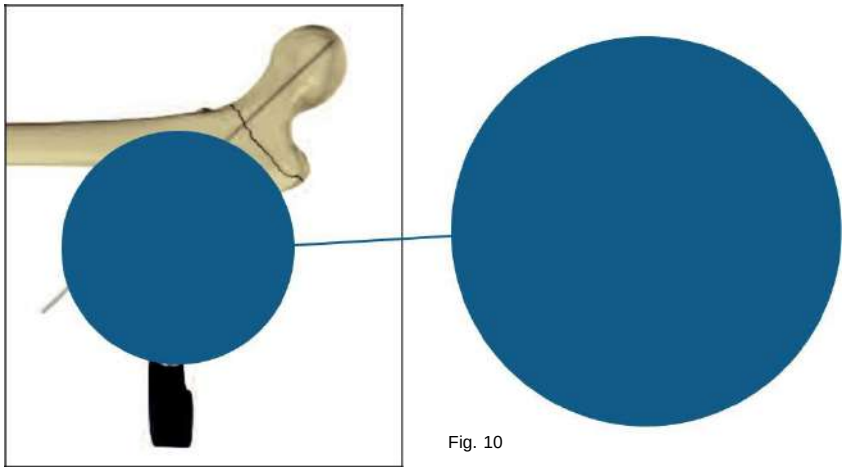


Fig. 9 Variable Angle Guide for Guide Pin Placement or Angle Measurement when the Guide Pin is inserted in “free hand technique”

Fig. 10

Guide Pin Insertion, continued

Frontal view

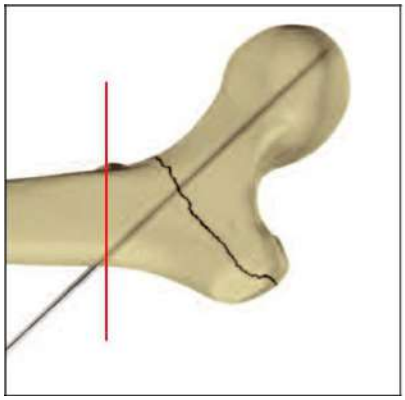


Fig. 11 A/P View

Lateral view

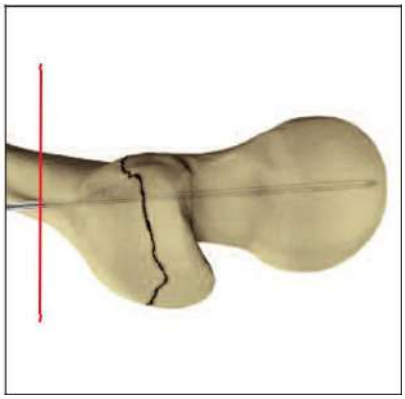


Fig. 12 Lateral View

While holding the appropriate angle guide firmly on the femoral shaft, the 2.8mm Guide Pin is inserted in the hole of the angle guide and advanced into the femoral head under image intensification until it reaches the subchondral bone in the center of the femoral head in both frontal and lateral views (Fig. 11 & 12).

If the Guide Pin is not positioned correctly, an additional pin can be inserted 5mm above or below the central position in the frontal plane, and 5mm anteriorly or posteriorly to the central position in the lateral plane, without removing the first Guide Pin (Fig. 13 & 14).

Note: To insert a second pin near the first one, use a Quick Coupling Chuck for 2.8mm Guide Pin (REF 704027) together with a 2.8mm Guide Pin with quick coupling fitting (REF 704012S), otherwise there is a risk that the power drill chuck will touch the first Guide Pin.

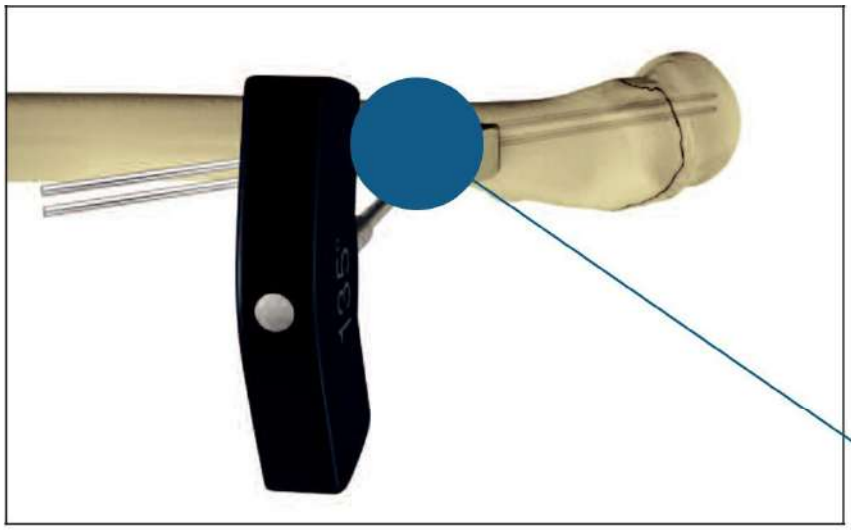


Fig. 13 Optional: Correction of Guide Pin placement possible using an additional Guide Pin: Lateral View

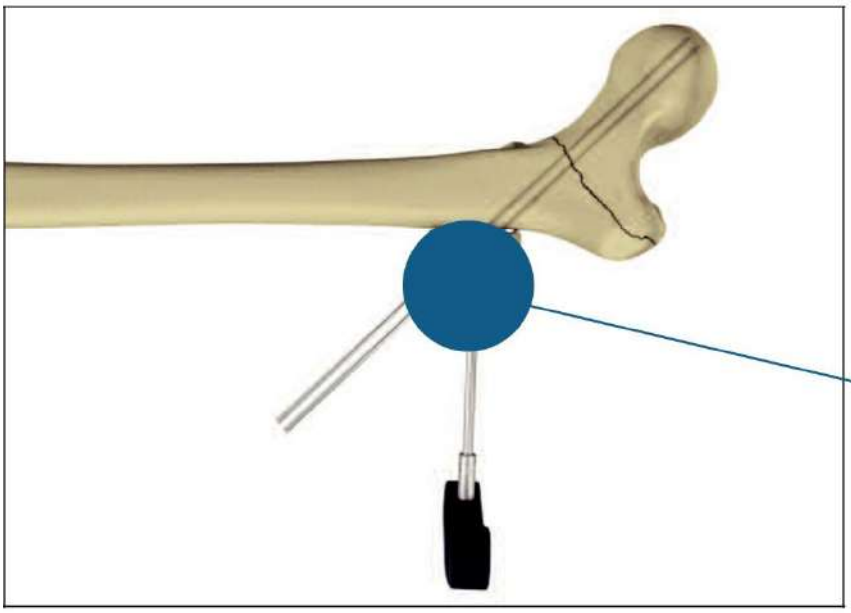


Fig. 14 Optional: Correction of Guide Pin placement possible using an additional Guide Pin: AP View

Guide Pin Insertion, continued

Freehand technique for Guide Pin placement:

Place a 2.8mm Guide Pin anterior to the neck of the femur (Fig. 15) and align it in the center of the head against the medial cortex by using image intensification.

A 3.2mm Drill Bit can be used to make an opening in the lateral cortex, allowing for easy insertion of the Guide Pin. Using image intensification, the Guide Pin is advanced until it reaches the subchondral bone in the femoral head. After confirming appropriate tip position of the Guide Pin on both frontal and lateral views, verify the appropriate plate angle by using the Variable Angle Guide. To unlock the mechanism, pull the cylinder of the guide (Fig. 16) and turn it by 90° (Fig. 17).

Slide the Variable Angle Guide over the Guide Pin and adjust it down to the lateral aspect of the femur (make sure that all the spikes are in contact with the bone shaft).
The arrow on the cylinder will indicate at which angle the Guide Pin has been inserted (Fig. 18), and therefore the angle of the barrel plate to be selected.

Fig. 15 Guide Pin anterior to the neck of the femur

Note: Be sure to verify that the set angle is not changed when the Variable Angle Guide is touching soft tissue. This may occur when the incision is made too small.

Fig. 16

Fig. 17

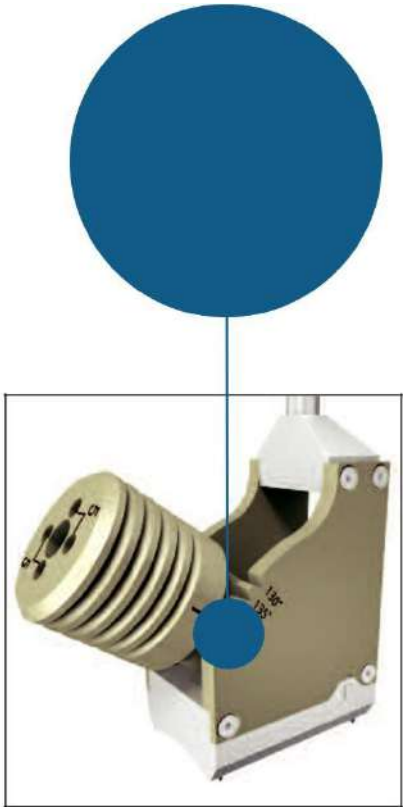


Fig. 18

Guide Pin Measurement

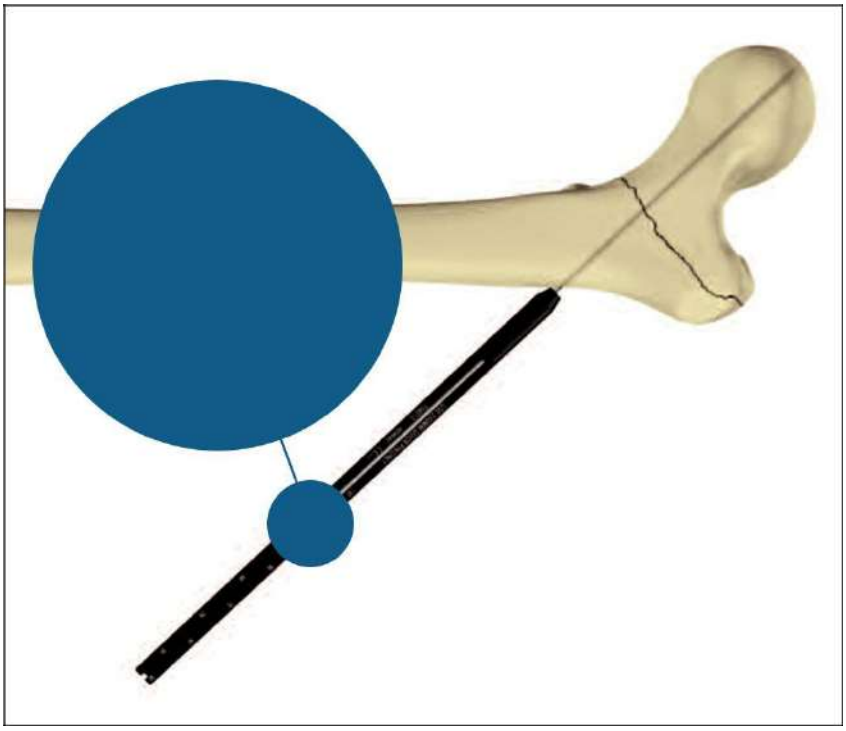


Fig. 19

The Depth Gauge indicates the exact length of the Guide Pin which has been inserted into the bone (Fig. 19). The surgeon must decide the depth to which the Lag Screw will be inserted.

The reaming depth is recommended to be approximately 10mm shorter than the Depth Gauge reading to permit the correct tip-apex distance.

How to select the correct length of the Lag Screw when applying compression:

The fracture must first be reduced anatomically. Compression may enhance the reduction but does not replace it.

Intra-operatively, once the femoral neck channel has been reamed, the surgeon must use image intensification to judge the amount of compression required.

The compression is limited firstly by the length of the Compression Screw threads (10mm) and secondly by the length of the Lag Screw chosen. The Lag Screw must be shorter than the reamed channel by the number of mm of compression required.

If, following the compression, a surgeon sees on the X-Ray that further compression is necessary but impossible due to the length of the implant and Compression Screw, he must remove the implant and choose a shorter length Lag Screw.

Any attempt to force compression can result in breakage of the Compression Screw.

Example without compression:

- Depth Gauge measurement: **110mm**
- Reamer depth setting: **100mm**
- Omega Plus Lag Screw length selected: **100mm**

Example with 5mm compression:

- Depth Gauge measurement: **110mm**
- Reamer depth setting: **100mm**
- Desired Compression: **5mm**
- Omega Plus Lag Screw length selected: **95mm**

Anti-Rotation Guide Pin Insertion

The Guide Pin Replacement Instrument can also be used to insert a second Guide Pin parallel to the primary Guide Pin, depending on the fracture pattern (Fig. 20).

The Guide Pin for the Lag Screw must be placed in an inferior position to allow space for placement of a second pin or screw, if the femoral neck is narrow.

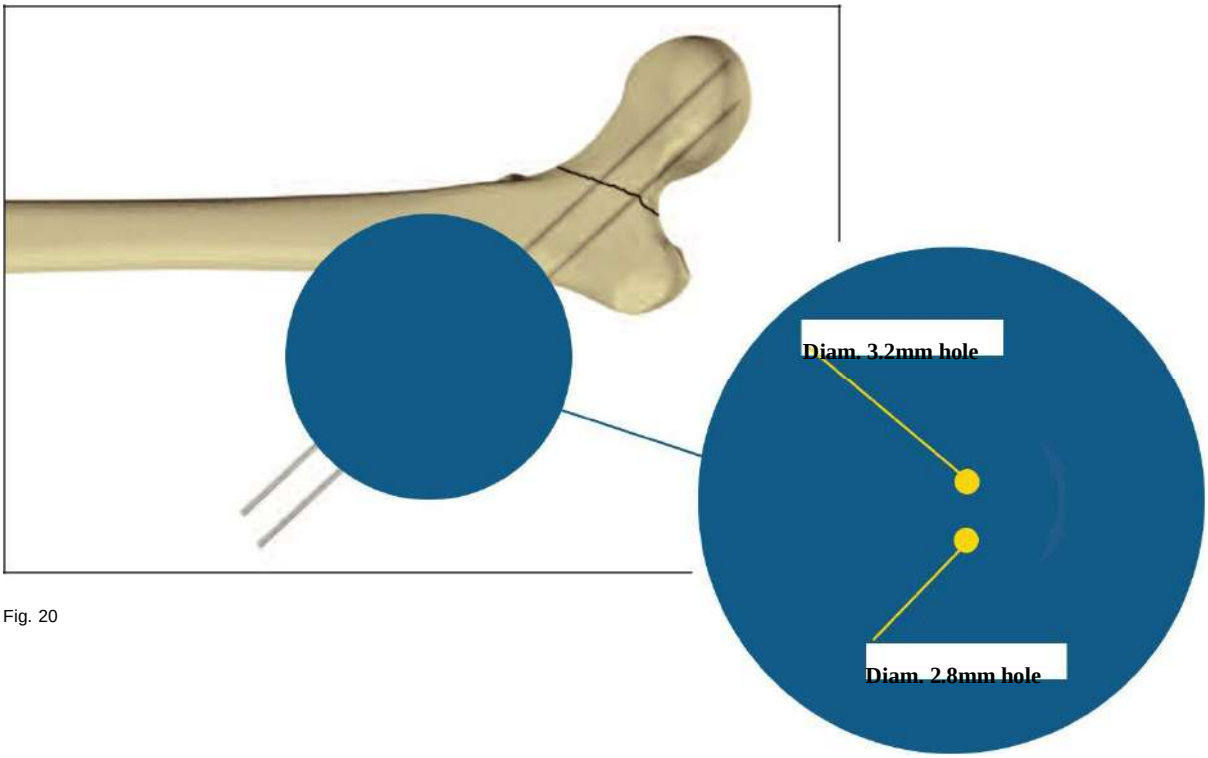


Fig. 20

This step is especially useful in providing temporary stability for femoral neck fractures and basal neck fractures, where the head could rotate during reaming or screw insertion.

Correct positioning of the anti-rotational wire can be done by rotating the instrument anteriorly or posteriorly (Fig. 20).

This instrument also accommodates a 3.2mm guide wire, should the surgeon wish to insert a 6.5mm Cannulated Screw for definitive rotational stability (Fig. 21). Alternatively to Cannultated Screw a Pin can be inserted as well.

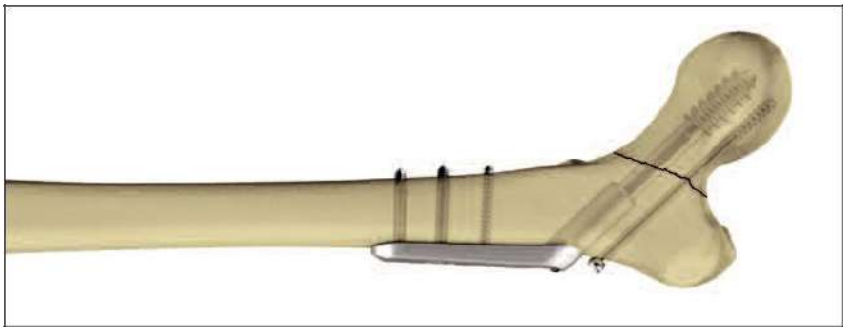


Fig. 21

Combination Reamer Assembly Instructions

Barrel Reamer, Standard

Barrel Reamer, Short

Step 1

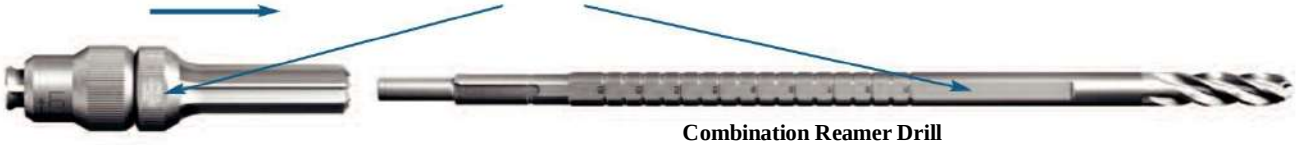
Select and assemble the Barrel Reamer.

Note: Choose the corresponding Barrel Reamer, i.e. Standard Barrel Reamer for Omega3 Plate with Standard Barrel, or the Short Barrel Reamer for Omega3 Plate with Short Barrel. The Stop Sleeve must be threaded until a mechanical stop is felt.

Step 2

Align the flat side of the Barrel Reamer to the flat side of the Combination Reamer Drill, and engage the Barrel Reamer over the coupling end of the Combination Reamer Drill.

Note: Flat sides must be aligned

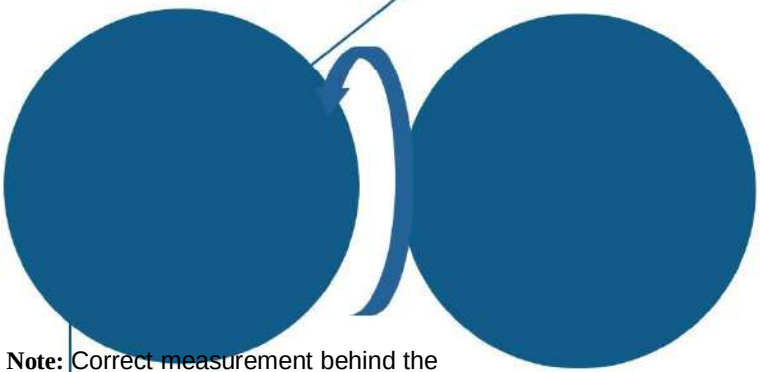


Combination Reamer Drill

Step 3

Slide the Barrel Reamer until the stop has been adjusted to the correct measurement behind the barrel. Lock the Barrel Reamer by turning the Stop Sleeve counter-clockwise until the Barrel Reamer is fixed to the Combination Reamer Drill.

Barrel Reamer Assembly



Note: Correct measurement behind the barrel, then lock the Stop Sleeve

Femoral Head / Neck Reaming

Select and assemble the correct Barrel Reamer (according to the standard or short barrel plate selected).

The Combination Reamer is set and locked by firmly turning the Stop Sleeve counter-clockwise at the predetermined depth setting (approximately 10mm less than the Guide Pin measurement).

Ream over the Guide Pin with the Combination Reamer until the stop reaches the lateral cortex (Fig. 22).

Remove the Combination Reamer while still reaming clockwise, in order to remove debris from the reamed canal.

Note: Guide Pins are not intended for re-use.
They are for single use only. Guide Pins may be damaged or bent during surgical procedures. If a Guide Pin is re-used, it may become lodged in the drill and could be advanced into the pelvis, damaging large blood vessels or vital organs.

Should the guide pin be inadvertently withdrawn, reverse the Guide Pin Replacement Instrument (Fig. 23), insert it into the femur, and reinsert the Guide Pin (Fig. 24).

Note for short barrel plates:

For more lateral intertrochanteric fractures or medial displacement osteotomies, the short barrel plates provide fixation without the barrel crossing the fracture.

Reaming is accomplished using the Short Barrel Reamer, following the same procedure for standard barrel reaming.

Fig. 22

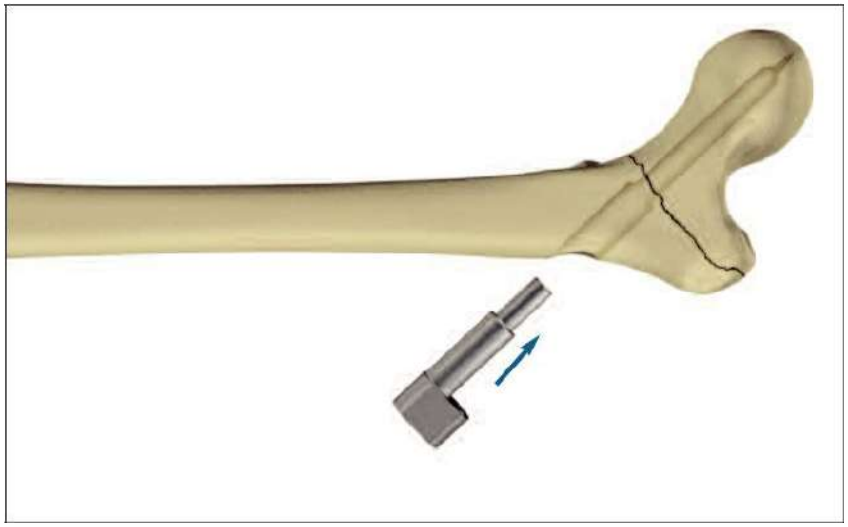


Fig. 23

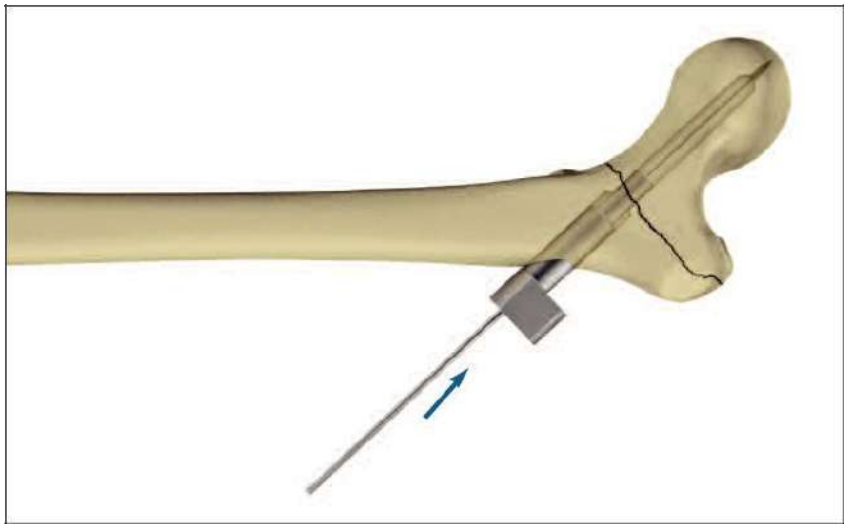


Fig. 24

Tapping for Lag Screw

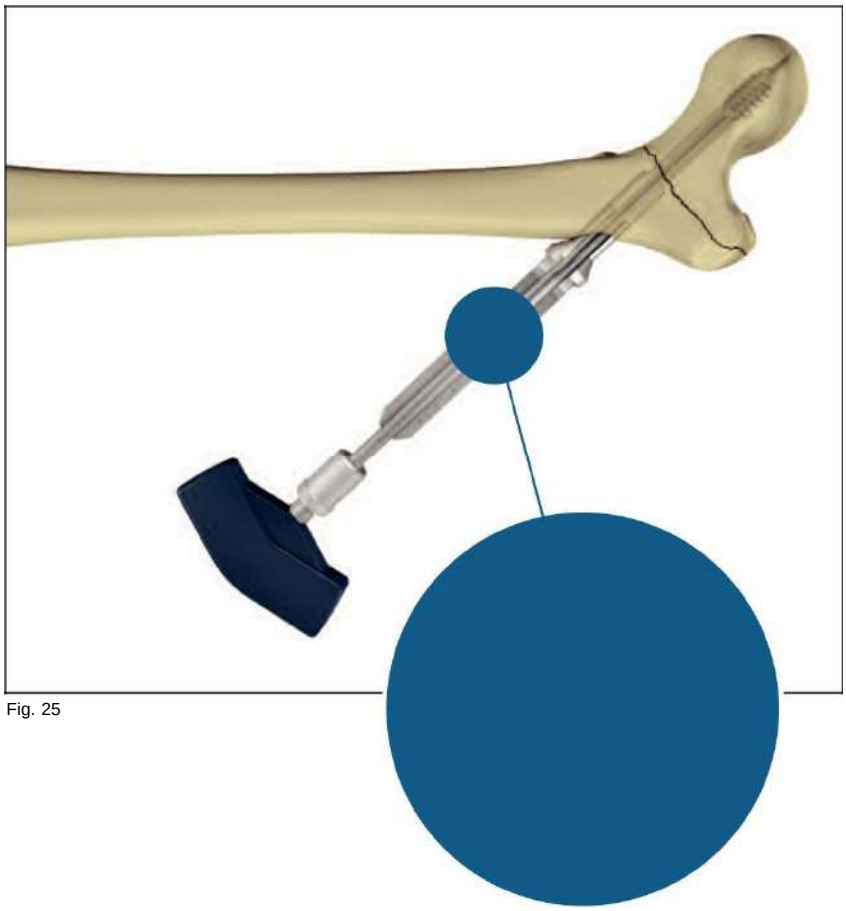


Fig. 25

The Lag Screw Tap should be used when good quality, dense bone is encountered; the Calibrated Tap Sleeve indicates the proper depth of the Tap.

The Tap is advanced until the indicator ring on the Tap reaches the correct depth marking on the Centering Sleeve (Fig. 25).

Note: If significant torque is required to tap very dense bone, consideration should be given to placing an antirotation guide-wire.

Example:

- Depth Gauge measurement: **110mm**
- Reamer depth setting: **100mm**
- Tapping depth: **100mm**
- Lag Screw length selected: **100mm**

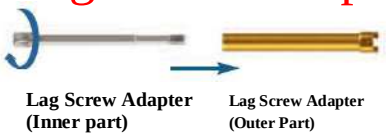
Lag Screw Tap Assembly

Push the quick coupling sleeve on the Large T-Handle and insert the Lag Screw Tap fitting into the coupling.

Assemble the Lag Screw Tap Sleeve to the Lag Screw Tap by aligning the flat sides of the Tap to the flat sides in the Tap Sleeve.

Lag Screw Instrument Assembly Instructions

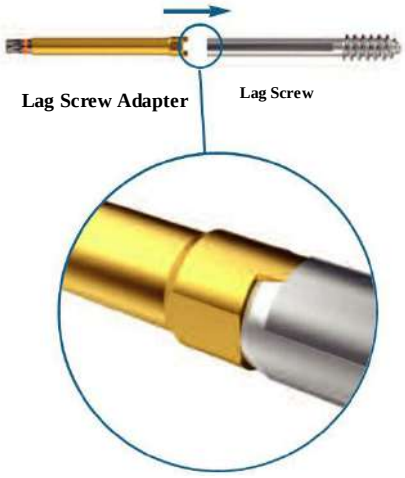
Lag Screw Adapter Assembly



Lag Screw Adapter (Inner part)

Lag Screw Adapter (Outer Part)

Thread the inner part of the Lag Screw Adapter through the outer part.



Lag Screw Adapter

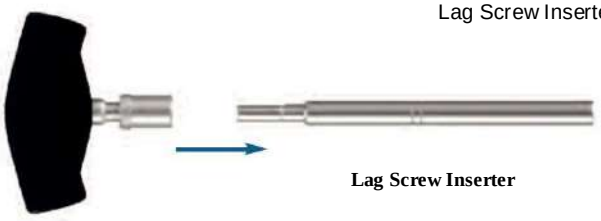
Lag Screw

Thread the assembly into the Lag Screw.

Lag Screw Inserter Assembly

Push the quick coupling sleeve on the Large T-Handle and insert the Lag Screw Inserter into the coupling.

Slide the Lag Screw Inserter Sleeve over the Lag Screw Inserter.



Lag Screw Inserter

Large T-Handle

Lag Screw Inserter Sleeve

Lag Screw Adapter Assembly

Lag Screw Insertion

Fig. 26

Select a Lag Screw of the appropriate length and assemble it to the Lag Screw Adapter. Join the Lag Screw Inserter Assembly to the Lag Screw Adapter Assembly. Insert the Lag Screw into the bone over the Guide Pin.

The Centering Sleeve on the Inserter Assembly is advanced into the pre-reamed hole, and the Lag Screw is driven into the prepared channel.

Advance the Lag Screw by turning and pushing the T-handle clockwise to its final position.

Depth of insertion of the Lag Screw is determined by observing the two depth indicator rings on the inserter (Fig. 26).

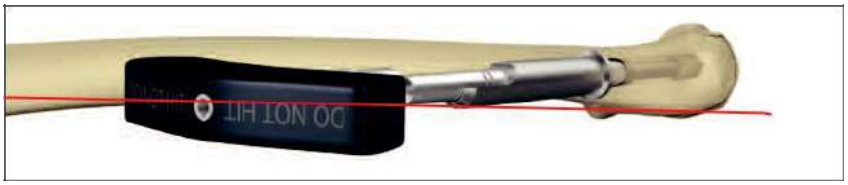


Fig. 27

The T-Handle of the insertion/ extraction wrench is aligned with the long axis of the femur in preparation for placement of the Hip Plate (Fig. 27).

Note: In this manner, the “flats” of the Lag Screw are in proper alignment with the barrel of the hip plate for the keyed system.

Depth Indicator Rings

Depth indicator rings measure desired compression.

For typical anatomy (135° head/neck angle), advance the Lag Screw Inserter Assembly until the ring marked “135°” reaches the zero mark on the Inserter.

No Compression, in case of 135° plate

5mm Compression, in case of 135° plate

10mm Compression, in case of 135° plate

For valgus anatomy (150° head/neck angle), advance the Lag Screw Inserter Assembly until the ring marked “150°” reaches the zero mark on the inserter.

Center the sleeve corresponding to the amount of compression desired.

Omega3 Hip Plate Insertion

Upon completion of Lag Screw insertion, the Lag Screw Inserter assembly is removed from the Lag Screw by pulling back, leaving the Lag Screw Adapter in place.

The selected Omega3 Hip Plate is now placed over the Lag Screw Adapter and advanced to engage the Lag Screw (Fig. 28).

Impaction of the fracture may be accomplished by using the Plate Impactor together with a hammer or mallet (Fig. 29).

Note: Use gentle hammering only - otherwise the impactor may be destroyed.

Unscrew the Lag Screw Adapter by hand and remove it. Then, remove the 2.8mm Guide Pin.

Note: All Guide Pins are for single use and therefore must be discarded at the end of the surgical procedure.

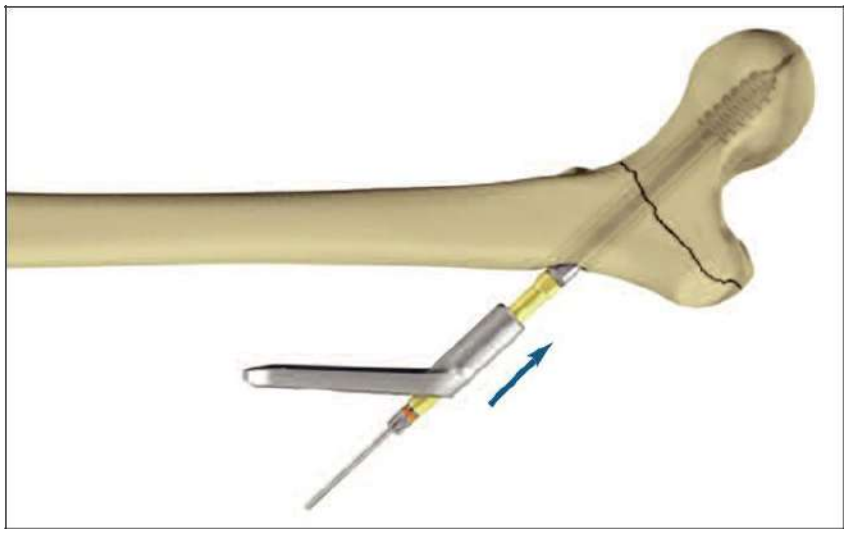


Fig. 28

Fig. 29

Omega3 Hip Plate Fixation with Standard Cortical Screws

Fig. 30

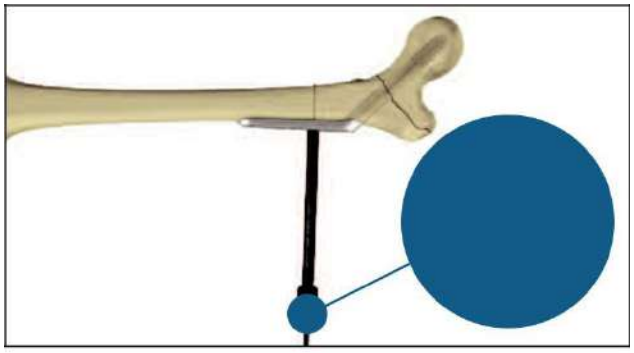
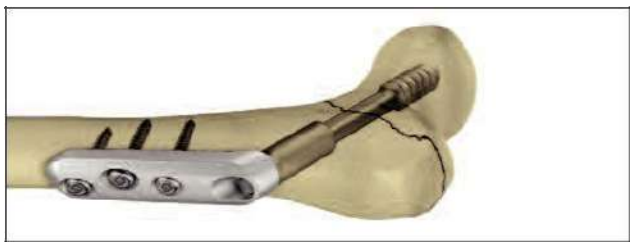


Fig. 31

Fig. 32

Fig. 33



The Omega3 System allows for two alternatives of plate fixation:
1. Fixation with 4.5mm Cortical Screws.
2. Axial stable fixation with 5.0mm Locking Inserts and Locking Screws. For axial stable fixation with Locking Inserts and Locking Screws please refer to the section on page 23. For Standard 4.5mm Cortical Screw fixation please follow the steps described below.

Using standard cortical screw insertion technique, fix the Omega3 Hip Plate to the femoral shaft beginning at the proximal end of the plate.

Note: When using the reduced skin incision technique, supplementary stab incisions can be performed for distal screw placements.

Use the drill bit through the drill sleeve with the green ring (Neutral) assembled to the Drill Guide Handle, to drill the bone screw holes (Fig. 30).

Note: If necessary it is possible to obtain compression of a shaft fracture or osteotomy site when using the drill sleeve with the yellow ring (1mm compression).

Determine appropriate Cortical Screw length using the Depth Gauge (Fig. 31). Always select a screw length one size longer in order to ensure the optimal bi-cortical purchase.

Insert the self tapping screw using the 3.5mm Hex Screwdriver with T-handle (Fig. 32).

Option

A 4.5mm Tap is available, to pre-tap in extremely hard cortical bone.
It is recommended to use the Tap in conjunction with a sleeve, if soft tissue is close to the Tap (Fig. 33).

Antero-lateral view of the Omega3 Hip Plate fixed with Standard 4.5mm Cortical Screws (Fig. 34).

Omega3 Hip Plate Fixation with Axial Stable Locking Screws

The shaft of the Omega3 Hip Plate is designed to accept Ø 4.5mm Standard Cortical Screws for neutral or compression plate attachment to the femoral bone according to standard technique described in this operative technique (page 22).

Alternatively, Ø 5.0mm Locking Inserts and Ø 5.0mm Locking Screws may be preferred for axial stable locking in patients with poor bone quality or to perform minimal invasive surgery with a shorter plate.

Locking Inserts and Screws may be used in conjunction with Standard Cortical Screws on the same hip plate.

However, Standard Cortical Screws may not be used in the Locking Inserts. Also it is mandatory to utilize the instrumentation designed specifically for the Locking Inserts and Screws.

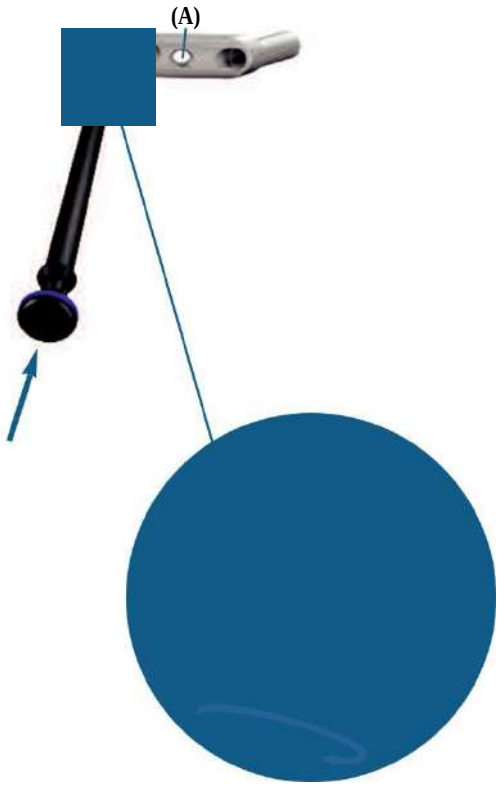
Step 1
Locking Insert Placement: Option1: Placement of the Locking Insert before Implantation of the Hip Plate

Before placing the Hip Plate over the Lag Screw onto the bone, thread a 5.0mm Locking Insert to the Inserter Instrument and push the Locking Insert into the chosen shaft hole of the Omega3 Hip Plate.

Note: The first, most proximal hole of the plate does not accept a Locking Insert **(A)**. A 4.5mm or 6.5mm bone screw always has to be used to align and advance the Hip Plate to the bone.

Note: Make sure that the Locking Insert is completely pushed into the shaft hole. Unthread the Inserter. Repeat this procedure with each hole you want to put a Locking Insert with Locking Screws.

Note: Do not attempt to push Locking Inserts into the plate holes with the Drill Sleeve.



Omega3 Hip Plate Fixation with Axial Stable Locking Screws ,continued

Fig. 35

Fig. 36

Fig. 37

Option2:
Placement
of the Locking Insert
after Implantation
of the Hip Plate (in situ):

If desired, a Locking Insert can be applied in a compression hole in the shaft of the plate intra-operatively (in situ) by using the Locking Insert Forceps, Holding Pin and Guide for Holding Pin.
When choosing this option, first implant the Hip Plate according to the description on page 22, perform a Cortical Screw insertion in the most proximal hole to advance the plate to the bone and then continue as described below with the Locking Inserts and Locking Screws.

First, the Holding Pin is inserted through the chosen hole using the Drill Sleeve for Holding Pin (Fig. 35). It is important to use the Guide as this centers the core hole for Locking Screw insertion after the Locking Insert is applied.
After inserting the Holding Pin bi-cortically, remove the Guide.

Next, place a Locking Insert on the end of the Forceps and slide the instrument over the Holding Pin down to the hole.
Last, apply the Locking Insert by triggering the forceps handle.
(Fig. 36).

Push the button on the Forceps to remove the device (Fig. 37).
At this time, remove the Holding Pin.

Omega3 Hip Plate Fixation with Axial Stable Locking Screws, continued

Step 2
Cortical Screw Insertion:

Perform Cortical Screw insertion in the first, most proximal hole according to the description on page 22 (Fig. 38).

Fig. 38

Step 3
Apply Drill Sleeve:

Thread the Drill Sleeve into the Locking Insert to expand its base within the plate hole, thus securing it.

For easier alignment, first push the Drill Sleeve down towards the plate and then rotate it to engage the thread (Fig. 39).

Fig. 39

Step 4
Drill:

Drill through both cortices of the femoral shaft using the 4.3mm Drill Bit attached to power (Fig. 40).

Fig. 40

Omega3 Hip Plate Fixation with Axial Stable Locking Screws, continued

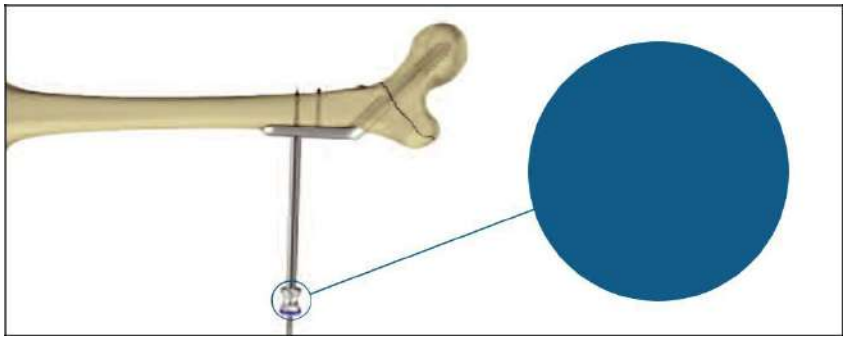


Fig. 41

Step 5
Screw Measurement:

Measure the required screw length by one of the two possibilities:

Option 1:

Measuring off the drill, using the calibrations marked on the drill (Fig. 41).

Note: Always select a screw length one size longer than measured, in order to ensure the optimal bi-cortical purchase.

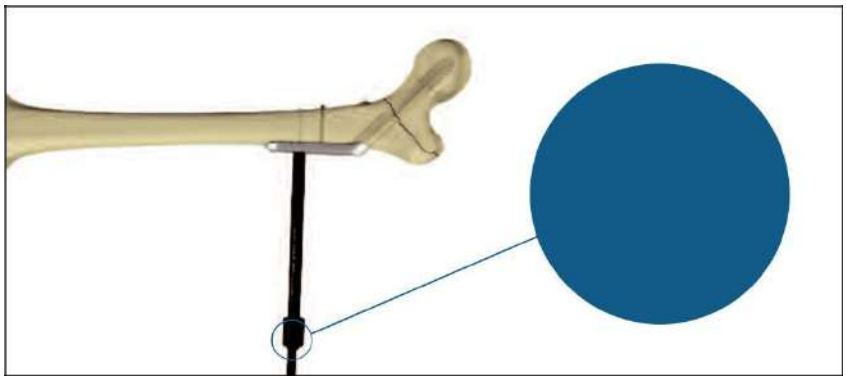


Fig. 42

Option 2:

Conventional direct, using the locking technique Direct Measuring Gauge through the Locking Insert and across both cortices (Fig. 42).

Note: Always select a screw length one size longer than measured in order to ensure the optimal bi-cortical purchase.

Omega3 Hip Plate Fixation with Axial Stable Locking Screws continued

Step 6
Screw Insertion:

Insert the Locking Screw into the Locking Insert, using the Screwdriver T20, AO fitting assembled with the Torque Limiter and the T-Handle, medium. Alternatively the Screwdriver T20, AO fitting can be used under direct power. However, final tightening always must be done manually.

The Locking Screw is adequately tightened when the Torque Limiter clicks at least once at the end of manual tightening (Fig. 43).

Note: The Torque Limiter is crucial to the mechanical integrity of the construct.

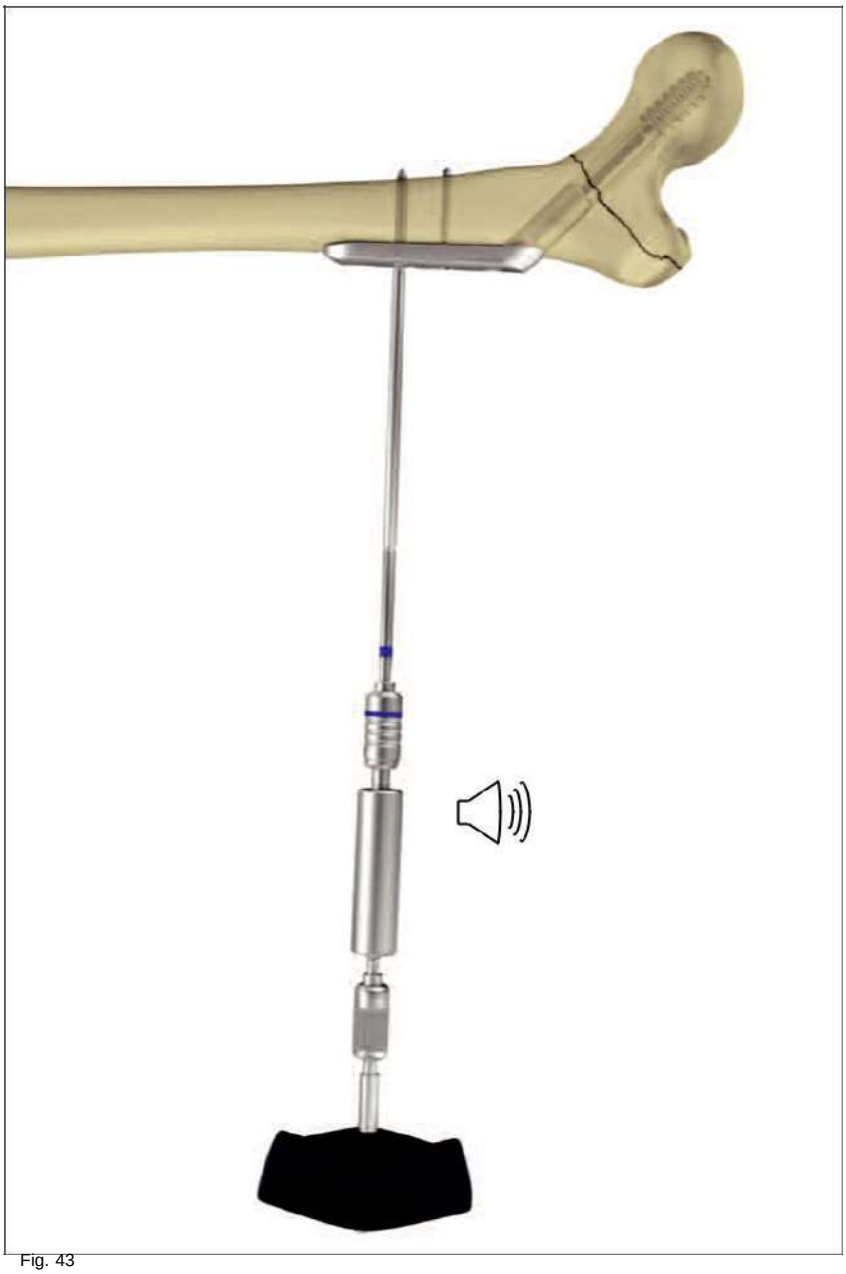


Fig. 43

Antero-lateral view of the Omega3 Hip Plate fixed with Lag Screw and axial stable Locking Inserts and Locking Screws (Fig. 44).

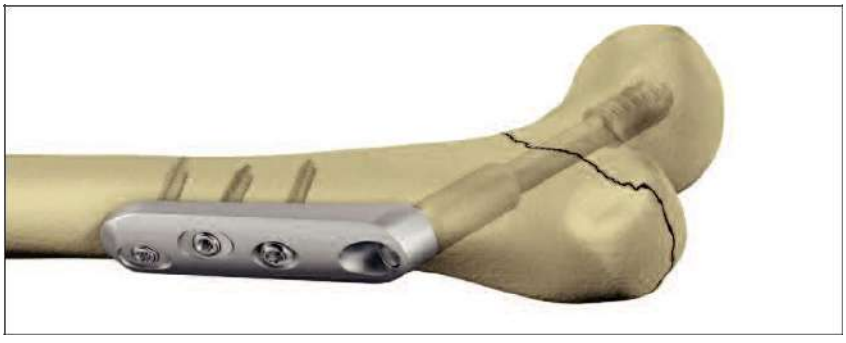


Fig. 44

Operative Technique

Extraction of Locking Inserts

Fig. 45

Fig. 46

Should removal of a Locking Insert be required then the following procedure should be used:

Step 1: Thread the central portion (Fig. 45) of the Extractor into the Locking Insert until it is fully seated.

Step 2: Turn the outer collet (Fig. 46) clockwise until it pulls the Locking Insert out of the plate.

Step 3: Remove the Locking Insert from the Extractor by threading it back onto the Locking Inserts Rack.

Note: Discard the Locking Insert as it cannot be reused.

Option: One-Step Lag Screw and Hip Plate Insertion

As an option to the standard technique, the One-Step Insertion Instruments may be used to insert the Hip Plate and the Lag Screw in a one-step procedure.

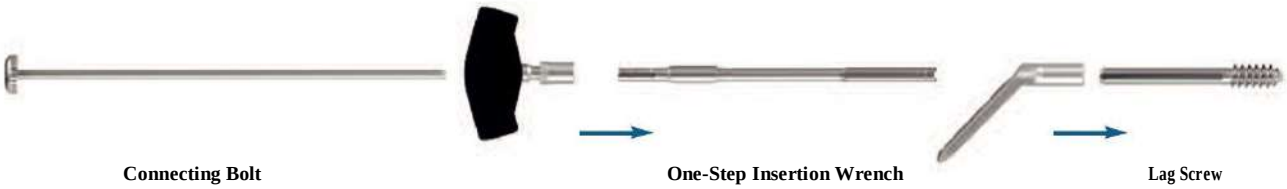
Instrument Assembly Instructions

Assemble the Large T-Handle to the One-Step Insertion Wrench as described in instruction below. Slide the One-Step Insertion Wrench through the barrel of the Hip Plate.

The Connecting Bolt is inserted through the Large T-Handle and threaded into the Lag Screw.

Prior to assembling the One-Step Insertion Sleeve to the One-Step Insertion Wrench/Hip plate assembly, ensure that the One-Step Insertion Sleeve is opened (mark on the inner sleeve lining up with the “open” mark on the outer sleeve).

Assemble the One-Step Insertion Sleeve to the One-Step Insertion Wrench between the Hip Plate and the Lag Screw, and lock the One-Step Insertion Sleeve.



Connecting Bolt

Large T-Handle

One-Step Insertion Wrench

Lag Screw

Omega3 Hip Plate

One-Step Insertion Sleeve

To lock the One-Step Insertion Sleeve, the inner and outer sleeve are twisted in opposite directions until the mark on the inner sleeve lines up with the “close” mark on the outer sleeve.

To unlock the sleeve, align the mark with the “open” mark on the outer sleeve.

One-Step Insertion Option, continued

Fig. 47

Assemble the appropriate Hip Plate and the Lag Screw onto the One-Step Insertion Wrench.

For typical anatomy (135° head/neck angle), advance the One-Step Insertion Wrench until the ring marked “135°” reaches the One-Step Insertion Sleeve.

For Valgus anatomy (150° head/neck angle), advance the One-Step Insertion Wrench until the ring marked “150°” reaches the One-Step Insertion Sleeve. Other angled plates should be inserted proportionally between the marks.

Fig. 48

Place the entire assembly over the Guide Pin and introduce it into the reamed hole (Fig. 47).

Advance the Lag Screw into the proximal femur to the predetermined depth and verify using image intensification.

At the conclusion of screw insertion, the handle of the One-Step Insertion Instrument must be aligned with the long axis of the femoral shaft to allow proper keying of the Lag Screw to the plate barrel (Fig. 48).

Remove the One-Step Insertion Sleeve and advance the Hip Plate onto the Lag Screw shaft.

The Plate Impactor should be used to fully seat the plate.

Unscrew the Connecting Bolt and remove the One-Step Insertion Wrench from the back of the Lag Screw; remove the 2.8mm Guide Pin.

Fig. 49

Stop inserting the Lag Screw when the 135° ring reaches the One-Step Insertion Sleeve (when a 135° Hip plate is selected)

Depth of insertion of the Lag Screw is determined by observing the two depth indicator rings on the One-Step Inserter Wrench (Fig. 49). From here the operation is continued with either the axial stable fixation of the Hip Plate using Locking Inserts and Locking Screws or the standard fixation with Cortical Screws (See page 22).

Fracture Compression

When all screws are inserted and tightened, and all traction is released, fracture compression can be accomplished by means of the Compression Screw (Fig. 50).

Caution should be used when applying compression. The Compression Screw exerts a powerful force that must be correlated with the quality of the bone.

The compression is limited firstly by the length of the compression screw threads (10mm) and secondly by the length of the implant chosen. The implant must be shorter than the reamed channel by the number of mm of compression required. **See example on page 14 and 20.**

If, following the compression, a surgeon sees on the X-Ray that further compression is necessary but impossible due to the length of the implant and compression screw, he must remove the implant and choose a shorter length implant. **Any attempt to force compression can result in breakage of the compression screw.**

The Compression Screw can also be used to protect the inner thread of the Lag Screw against soft tissue ingrowth, and it also prevents the Lag Screw from any medial migration.

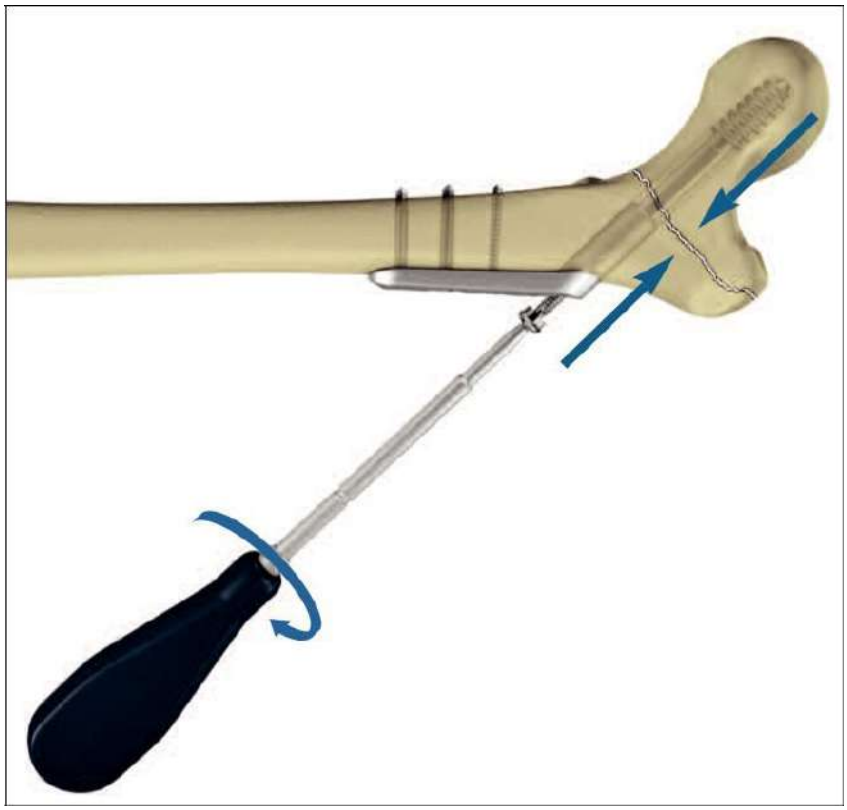


Fig. 50

Closing the Wound

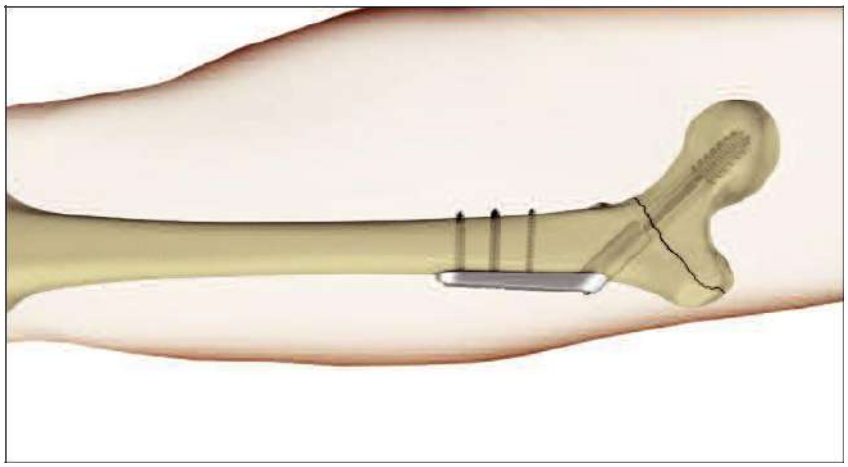


Fig. 51

Closure of the wound is done in layers, closing separately the fascia of the vastus lateralis muscle and the facia lata. Carefully reapproximate the subcutaneous tissue and the skin (Fig. 51).

Implant Removal

Fig. 52

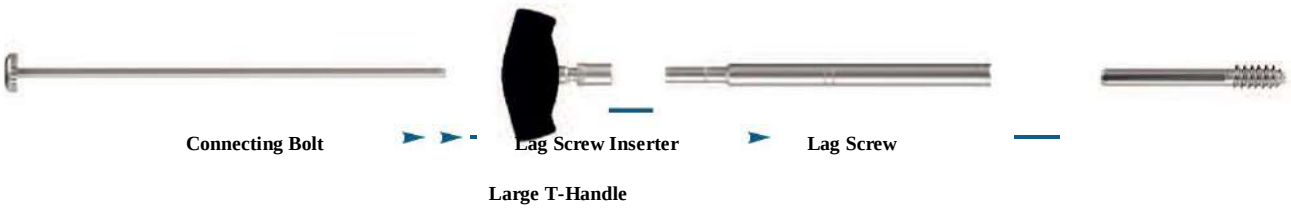
Should the need arise for hardware removal, the Lag Screw is extracted after removal of the Hip Plate through use of the Large T-Handle connected to the Lag Screw Inserter and the Connecting Bolt.
The T-Handle is turned counter-clockwise (Fig. 52).

Note: A guide wire can be placed into the screw to aid in alignment of the T-Handle.

Lag Screw Removal Assembly

Assemble the Large T-handle to the Lag Screw Inserter as described in instruction above.

The Connecting Bolt is inserted through the Large T-handle and threaded in to the Lag Screw.



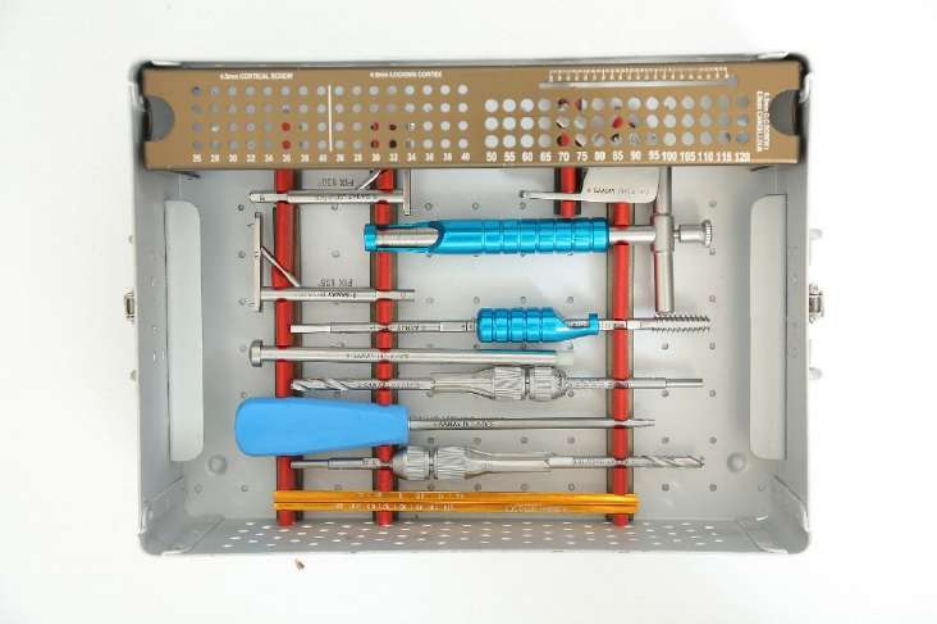
SAMAY Surgical

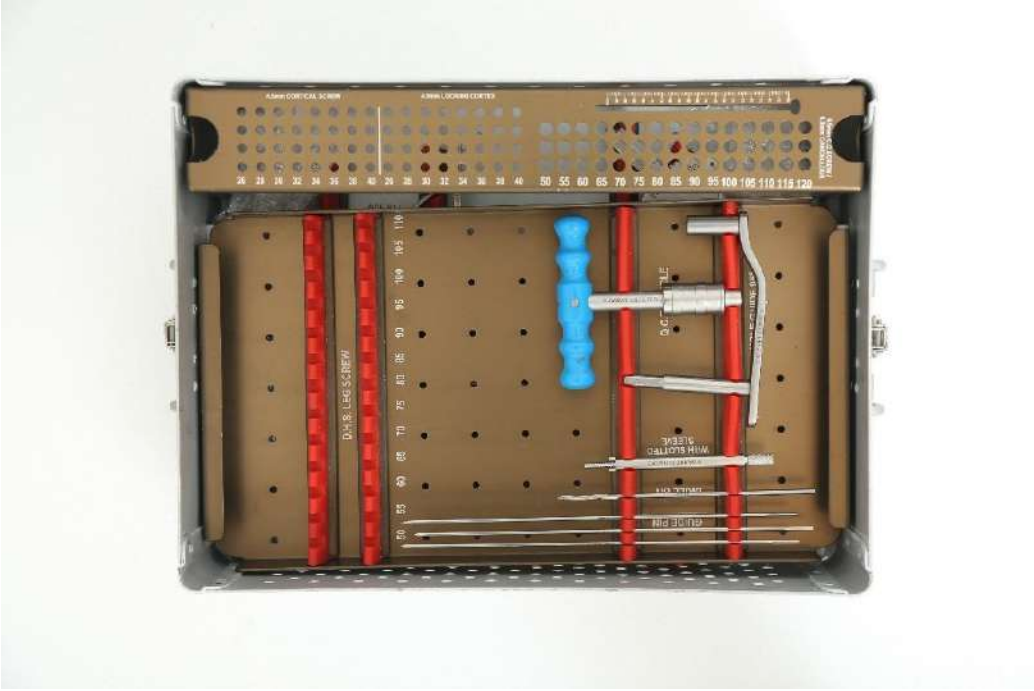
Ordering Information

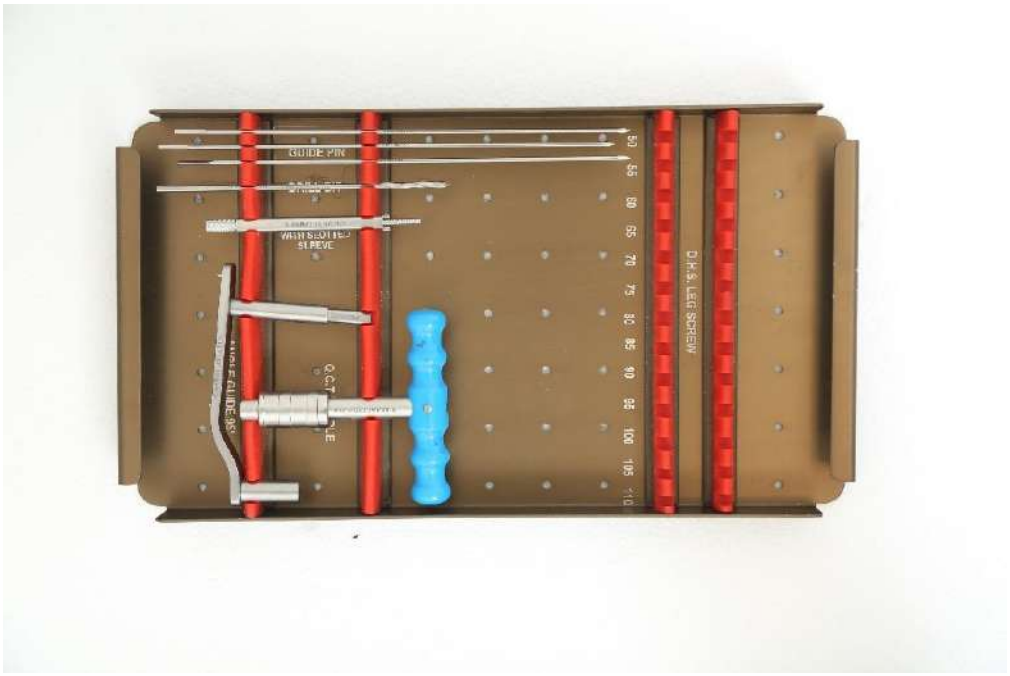
REF	Description
Cases and Trays	
Large Metal Case *	
	Omega3 Large Metal Case, empty Omega3 Large Metal Case Lid
	Basic Lag Screw Tray
	Omega3 Basic Lag Screw Tray, empty Omega3 Basic Lag Screw Lid Omega3 Basic Silicone Mat Omega3 Cortical Screw Rack

	DHS/DCS INSTRUMENTS
SS 13005	GUIDE PIN WITH THREADED TIP
SS 13010	DHS ANGLE GUIDE
SS 13015	T- HANDLE WITH QUICK COUPLING
SS 13020	DIRECT MEASURING DEVICE
SS 13025	DHS TRIPPLE REAMER
SS 13030	WRENCH FOR DHS SCREW
SS 13035	DHS IMPACTOR
SS 13040	DHS TAP
SS 13045	CENTRIC SLEEVE FOR DHS TAP
SS 13050	CENTRIC SLEEVE FOR DHS WRENCH
SS 13055	COUPLIMG SCREW FOR INSERTING DHS SCREW
SS 13060	GUIDE SHAFT FOR COUPLING SCREW
SS 13065	LONG COUPLING SCREW FOR DHS SCREW REMOVAL
SS 13070	STYLET
SS 13075	DCS TRIPPLE REMER
SS 13080	DCS ANGLE GUIDE
SS 13085	DHS TRIPPLE REAMER - SHORT REAMER

DHS INSTRUMENT SET






GUIDE PIN
D.H.S. LAG SCREW

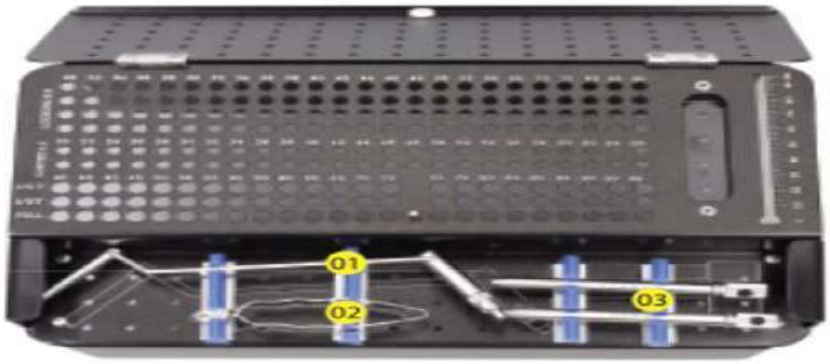

SAMAY

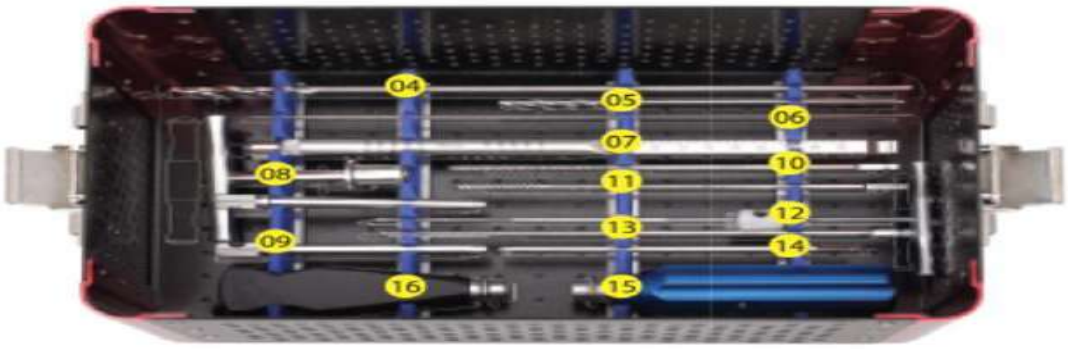
Large Fragments Sets	Size
Drill Bit	3.2*115mm
Drill Bit	4.5*115mm
Countersink Drill	Large
Cortex screw tap	4.5mm
Cancellous screw tap	6.5mm
Screw forceps	Large
Dual-use Drill Guide	3.2mm
Double drill guide	4.5/6.5mm
Double drill guide	3.2/4.5mm
Model	12*120mm
Model	12*155mm
Model	12*212mm
Depth Gauge	90mm
Anti-slip Screw Extractor	Large
Trephining	8mm
Hex screwdriver	3.5mm
Reduction forceps with points	210mm
Reduction forceps	225mm large
Self-centering Bone Forceps	260mm
Periosteal Elevator	12/15mm
Retractor	18/42mm
Plate Bender	L/R
Screw tray	
Instrument Case	


Large Fragment Instrument Set

.

Large Locking Instrument Set	Size
Double drill guide	3.2mm
Screw clamp	
Pin drill sleeve	2.0mm
Drill bit	4.3mm
Drill bit	3.2mm
Threaded guide pin	2.0*250mm
Depth Gauge	90mm
T quick coupling handle	
Pin drill sleeve	4.3mm
Cortex screw tap	4.5mm
Cancellous screw tap	6.5mm
Lift drill	
Locking screw tap	5.0mm
Quick coupling screwdriver	SW3.5
Torque handle	4.0N.M
Screw tray and box	





Ordering Information – Implants Long Barrel

SS 152	DHS Barrel Plate DCP Hole 130º (Barrel Length 38mm)
SS 152-203	03 Hole
SS 152-204	04 Hole
SS 152-205	05 Hole
SS 152-206	06 Hole
SS 152-207	07 Hole
SS 152-208	08 Hole
SS 152-209	09 Hole
SS 152-210	10 Hole
SS 152-212	12 Hole
SS 152-214	14 Hole
SS 152-216	16 Hole
SS 152	**DHS Barrel Plate DCP Hole 135º (Barrel Length 38mm)**
SS 152-303	03 Hole
SS 152-304	04 Hole
SS 152-305	05 Hole
SS 152-306	06 Hole
SS 152-307	07 Hole
SS 152-308	08 Hole
SS 152-309	09 Hole
SS 152-310	10 Hole
SS 152-312	12 Hole
SS 152-314	14 Hole
SS 152-316	16 Hole
SS 152	**DHS Barrel Plate DCP Hole 140º (Barrel Length 38mm)**
SS 152-403	03 Hole
SS 152-404	04 Hole
SS 152-405	05 Hole
SS 152-406	06 Hole
SS 152-407	07 Hole
SS 152-408	08 Hole
SS 152-409	09 Hole
SS 152-410	10 Hole
SS 152-412	12 Hole
SS 152-414	14 Hole
SS 152-416	16 Hole

Short Barrel

SS 152	DHS Barrel Plate DCP Hole 130º (Barrel Length 25MM)
SS 152-203	03 Hole
SS 152-204	04 Hole
SS 152-205	05 Hole
SS 152-206	06 Hole
SS 152-207	07 Hole
SS 152-208	08 Hole
SS 152-209	09 Hole
SS 152-210	10 Hole
SS 152-212	12 Hole
SS 152-214	14 Hole
SS 152-216	16 Hole
SS 152	**DHS Barrel Plate DCP Hole 135º (Barrel Length 25MM)**
SS 152-303	03 Hole
SS 152-304	04 Hole
SS 152-305	05 Hole
SS 152-306	06 Hole
SS 152-307	07 Hole
SS 152-308	08 Hole
SS 152-309	09 Hole
SS 152-310	10 Hole
SS 152-312	12 Hole
SS 152-314	14 Hole
SS 152-316	16 Hole
SS 152	**DHS Barrel Plate DCP Hole 140º (Barrel Length 25MM)**
SS 152-403	03 Hole
SS 152-404	04 Hole
SS 152-405	05 Hole
SS 152-406	06 Hole
SS 152-407	07 Hole
SS 152-408	08 Hole
SS 152-409	09 Hole
SS 152-410	10 Hole
SS 152-412	12 Hole
SS 152-414	14 Hole
SS 152-416	16 Hole

Lag Screw

SS 155	DHS Lag Screw
SS 155-050	50.0 mm
SS 155-055	55.0 mm
SS 155-060	60.0 mm
SS 155-065	65.0 mm
SS 155-070	70.0 mm
SS 155-075	75.0 mm
SS 155-080	80.0 mm
SS 155-085	85.0 mm
SS 155-090	90.0 mm
SS 155-095	95.0 mm
SS 155-100	100.0 mm
SS 155-105	105.0 mm
SS 155-110	110.0 mm
SS 155-115	115.0 mm
SS 155-120	120.0 mm

Compression Screw

SS 156	DHS Compression Screw
SS 156-036	36.0 mm

4.5 mm Cortex screw

SS 109	4.5 mm CORTEX SCREW (Pitch 1.75)
SS 109-010	10.0 mm
SS 109-012	12.0 mm
SS 109-014	14.0 mm
SS 109-016	16.0 mm
SS 109-018	18.0 mm
SS 109-020	20.0 mm
SS 109-022	22.0 mm
SS 109-024	24.0 mm
SS 109-026	26.0 mm
SS 109-028	28.0 mm
SS 109-030	30.0 mm
SS 109-032	32.0 mm
SS 109-034	34.0 mm
SS 109-036	36.0 mm
SS 109-038	38.0 mm
SS 109-040	40.0 mm
SS 109-042	42.0 mm
SS 109-044	44.0 mm
SS 109-046	46.0 mm
SS 109-048	48.0 mm
SS 109-050	50.0 mm
SS 109-052	52.0 mm
SS 109-054	54.0 mm
SS 109-056	56.0 mm
SS 109-058	58.0 mm
SS 109-060	60.0 mm
SS 109-062	62.0 mm
SS 109-064	64.0 mm
SS 109-066	66.0 mm
SS 109-068	68.0 mm
SS 109-070	70.0 mm
SS 109-075	75.0 mm

SAMAY Surgical

5.0 mm Locking Screw

SS 305	5.0 mm Locking Screw
SS 305-016	16.0 mm
SS 305-018	18.0 mm
SS 305-020	20.0 mm
SS 305-022	22.0 mm
SS 305-024	24.0 mm
SS 305-026	26.0 mm
SS 305-028	28.0 mm
SS 305-030	30.0 mm
SS 305-032	32.0 mm
SS 305-034	34.0 mm
SS 305-036	36.0 mm
SS 305-038	38.0 mm
SS 305-040	40.0 mm
SS 305-042	42.0 mm
SS 305-044	44.0 mm
SS 305-046	46.0 mm
SS 305-048	48.0 mm
SS 305-050	50.0 mm
SS 305-052	52.0 mm
SS 305-054	54.0 mm
SS 305-056	56.0 mm
SS 305-058	58.0 mm
SS 305-060	60.0 mm
SS 305-062	62.0 mm
SS 305-064	64.0 mm
SS 305-066	66.0 mm
SS 305-068	68.0 mm
SS 305-070	70.0 mm
SS 305-075	75.0 mm
SS 305-080	80.0 mm
SS 305-085	85.0 mm
SS 305-090	90.0 mm

6.5 mm Cancellous Locking Screw Fully Threaded

SS 309	6.5 mm CANCELLOUS LOCKING SCREW Fully mm THREADED
SS 309-020	20.0 mm
SS 309-025	25.0 mm
SS 309-030	30.0 mm
SS 309-035	35.0 mm
SS 309-040	40.0 mm
SS 309-045	45.0 mm
SS 309-050	50.0 mm
SS 309-055	55.0 mm
SS 309-060	60.0 mm
SS 309-065	65.0 mm
SS 309-070	70.0 mm
SS 309-075	75.0 mm
SS 309-080	80.0 mm
SS 309-085	85.0 mm
SS 309-090	90.0 mm
SS 309-095	95.0 mm
SS 309-100	100.0 mm

5.0 mm Cancellous Locking Screw (Full Thread)

SS 305	5.0 mm Cancellous Locking Screw (Full Thread)
SS 305-125	25.0 mm
SS 305-130	30.0 mm
SS 305-135	35.0 mm
SS 305-140	40.0 mm
SS 305-145	45.0 mm
SS 305-150	50.0 mm
SS 305-155	55.0 mm
SS 305-160	60.0 mm
SS 305-165	65.0 mm
SS 305-170	70.0 mm
SS 305-175	75.0 mm
SS 305-180	80.0 mm
SS 305-185	85.0 mm
SS 305-190	90.0 mm
SS 305-195	95.0 mm
SS 305-196	100 mm

SAMAY Surgical

6.5 mm Cannulated Cancellous Screw

32mm Threaded

SS 119	6.5 mm CANNULATED CANCELLOUS SCREW 32.0 mm THREADED
SS 119-035	35.0 mm
SS 119-040	40.0 mm
SS 119-045	45.0 mm
SS 119-050	50.0 mm
SS 119-055	55.0 mm
SS 119-060	60.0 mm
SS 119-065	65.0 mm
SS 119-070	70.0 mm
SS 119-075	75.0 mm
SS 119-080	80.0 mm
SS 119-085	85.0 mm
SS 119-090	90.0 mm
SS 119-095	95.0 mm
SS 119-100	100.0 mm
SS 119-105	105.0 mm
SS 119-110	110.0 mm
SS 119-115	115.0 mm
SS 119-120	120.0 mm

SAMAY Surgical

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SAMAY SURGICAL

P.F.N Nail

Surgical Technique

PFN – Proximal Femoral Nail

Surgical Technique

SS 510	Instrument Set For Proximal Femoral Nail (P
SS 510-001	Jig
SS 510-002	Threaded Bolt
SS 510-003	Small Hummer Unit with Nut
SS 510-004	Extractor Rod
SS 510-005	Round Hummer
SS 510-006	Protection Sleeve 12mm
SS 510-007	Protection Sleeve 10mm
SS 510-008	Drill Sleeve for 4.0mm Drill
SS 510-009	Guide Wire Sleeve 1.8mm for 12mm
SS 510-010	Guide Wire Sleeve 1.8mm for 10mm
SS 510-011	Pointer Long
SS 510-012	T-Handle
SS 510-013	Spanner Ordinary (18 x 19) 01
SS 510-014	Spanner Ordinary (18 x 19) 02
SS 510-015	C.C Screw Driver for 5.0mm Hex (Long)
SS 510-016	Guide Wire Simple 2.0mm x 16" Long 01
SS 510-017	Guide Wire Simple 2.0mm x 16" Long 02
SS 510-018	Guide Wire Threaded 2.0mm x 16" Long 01
SS 510-019	Guide Wire Threaded 2.0mm x 16" Long 02
SS 510-020	C.C Drill Bit Long With Q/C for 8.0mm Screw
SS 510-021	C.C Drill Bit Long With Q/C for 6.2mm Screw
SS 510-022	C.C. Reamer with Q/C 15mm
SS 510-023	T-Handle for Drill Bits / Taps Q/C
SS 510-024	Depth Gauge (Long)
SS 510-025	Screw Driver for 4.5mm Hex (Long)
SS 510-026	K. Nail Awl Diamond Pointer
SS 510-027	K. Nail Tissue Protector
SS 510-028	Drill Bits S.S. 4mm x 10"
SS 510-029	Box for Nail & Instruments (18 Inch)

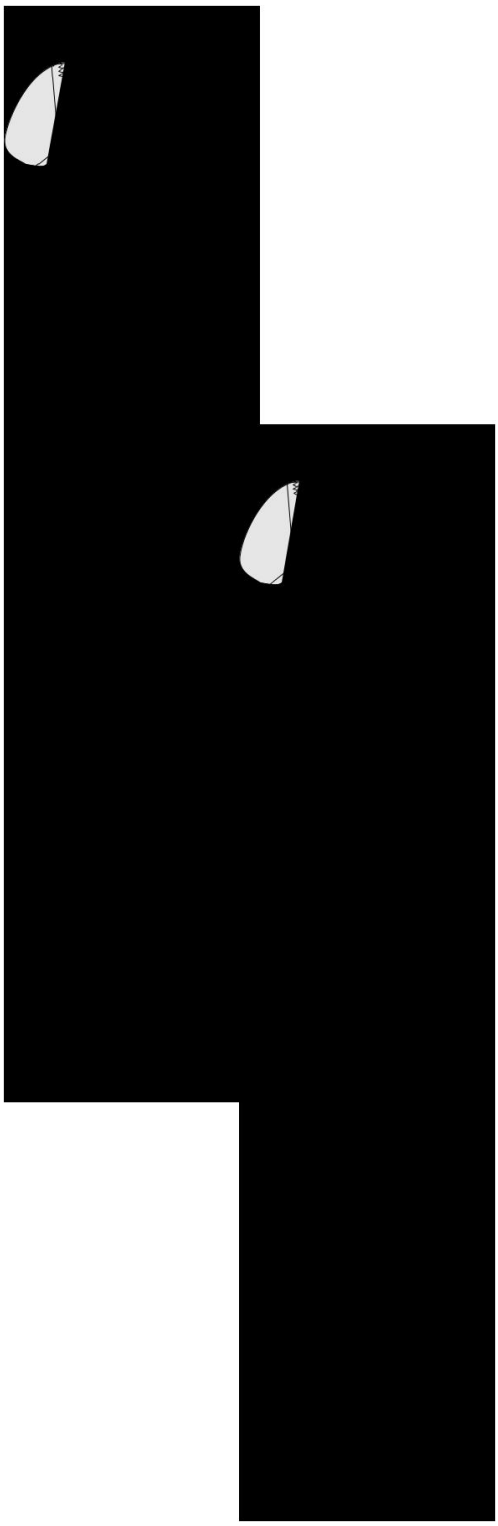
Proximal Femoral Nail –

Table of contents

Warning

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

Indications/Contraindications



Standard PFN

Indications

- Per trochanteric fractures
- Intertrochanteric fractures
- High sub trochanteric fractures

Contraindications

- Low sub trochanteric fractures
- Femoral shaft fractures
- Isolated or combined medial femoral neck fractures

Long PFN

Indications

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

Contraindications

- Isolated or combined medial femoral neck fractures

Range of indications

Implants for PFN Short Nail

End Cap

- Proximal diameter 14.0mm

- Self-tapping 6.4mm Hip Pin
- Lengths 60–120mm (<5mm>)
- For true rotational stability
- Featuring insertion safety stop
- CCD angle for Short nail130°/135
- Self-tapping 8.0mm Femoral Neck Screw
- Lengths 60–120mm (<5mm>)
- Featuring insertion safety stop
- Anatomical 5° ML angle
- Distal diameters for Short Nail of 9,10,11,12, and enable unreamed insertion

- 4.9mm Locking Bolt
- Lengths 20-70mm(<2mm>)

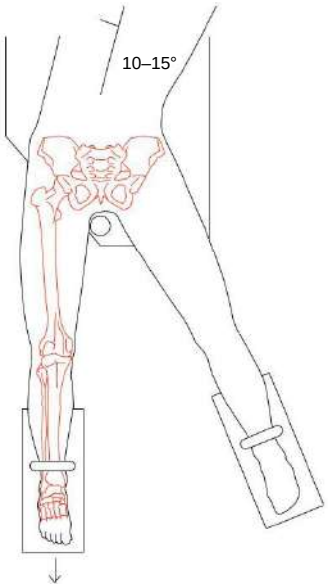
- The PFN is available in Titanium & stainless steel
- Total length: 250mm (Short P.F.N Nail)

Code	Product Description
SS 207	**Proximal Femoral Nail (P.F.N), (Shot) 135^0 25cm**
SS 207-025	9 mm Dia
SS 207-125	10 mm Dia
SS 207-225	11 mm Dia
SS 207-425	12 mm Dia
SS 207	**Proximal Femoral Nail (P.F.N), (Shot) 130^0 25cm**
SS 207-525	9 mm Dia
SS 207-625	10 mm Dia
SS 207-725	11 mm Dia
SS 207-825	12 mm Dia

Quick Steps for Standard PFN

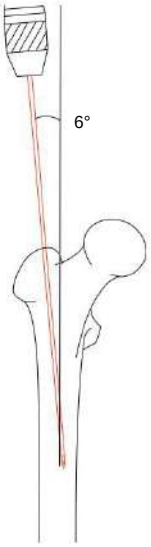
Preparation

A Patient positioning



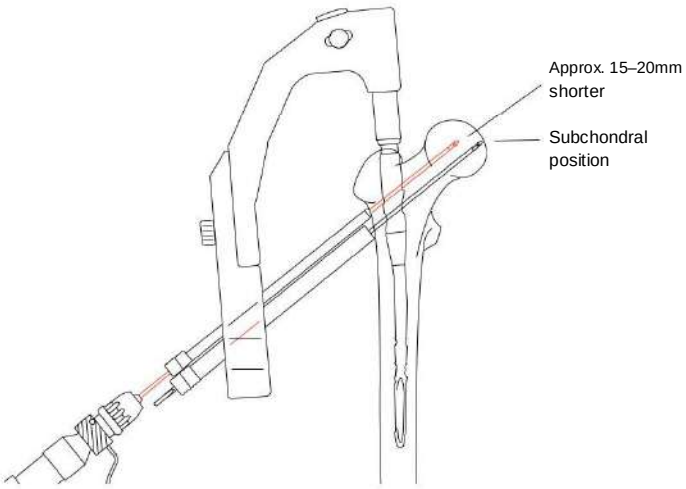
Insertion of Proximal Femoral Nail

A Insertion of guide wire for femur opening

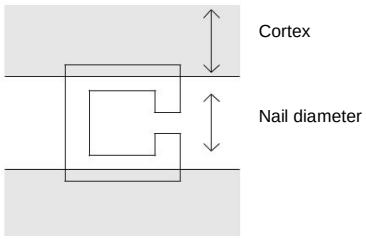


Position guide wires

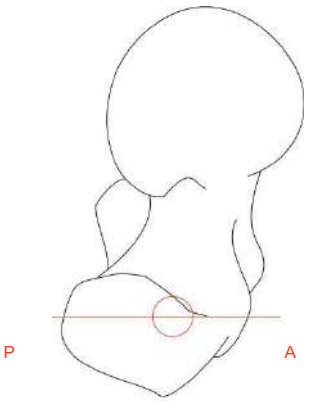
A Insertion of guide wires for femoral neck screw and hip pin



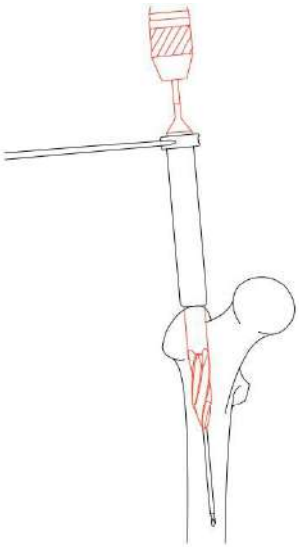
B Preoperative planning



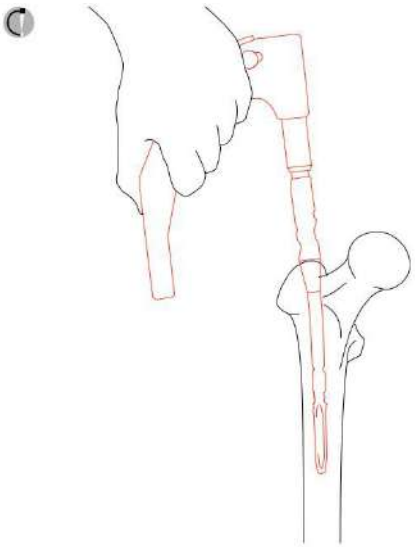
C Insertion point



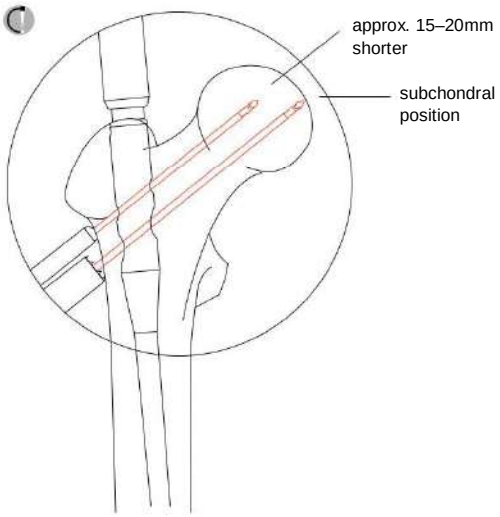
B Open femur



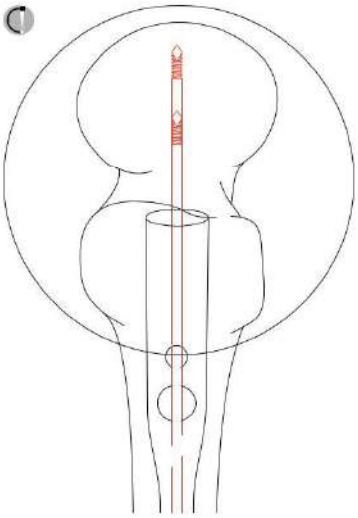
C Insertion of Proximal Femoral Nail



B Image intesifier control (AP)

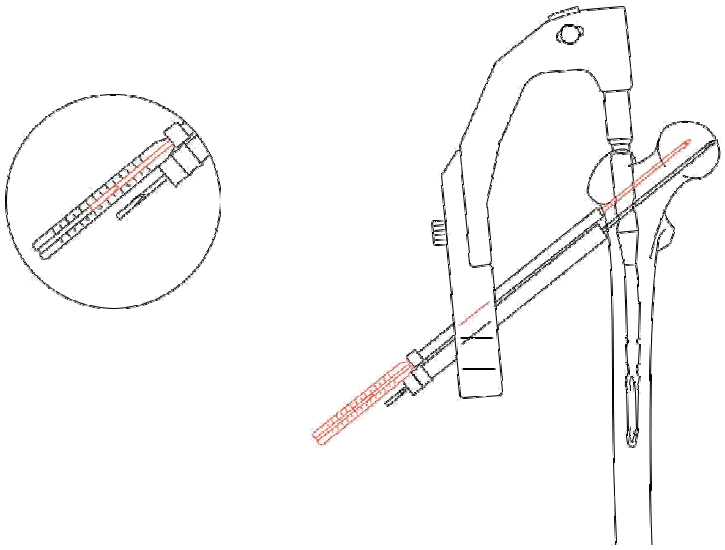


C Image intensifier control (laterally)



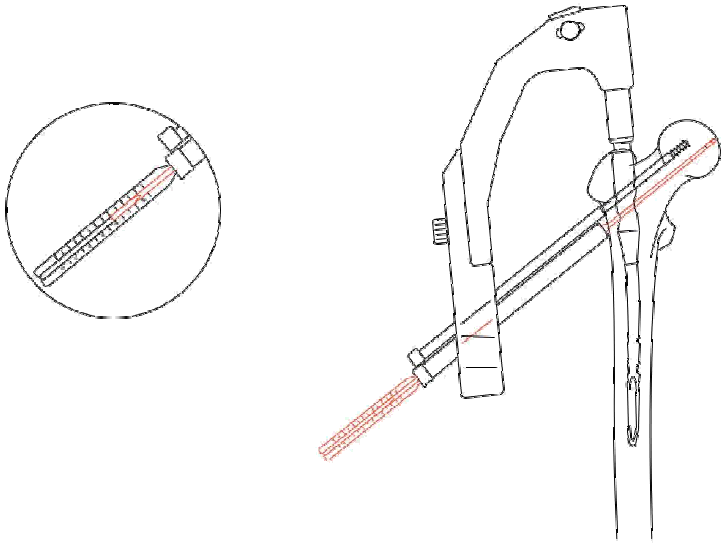
Insertion of hip pin

A Measure length of hip pin



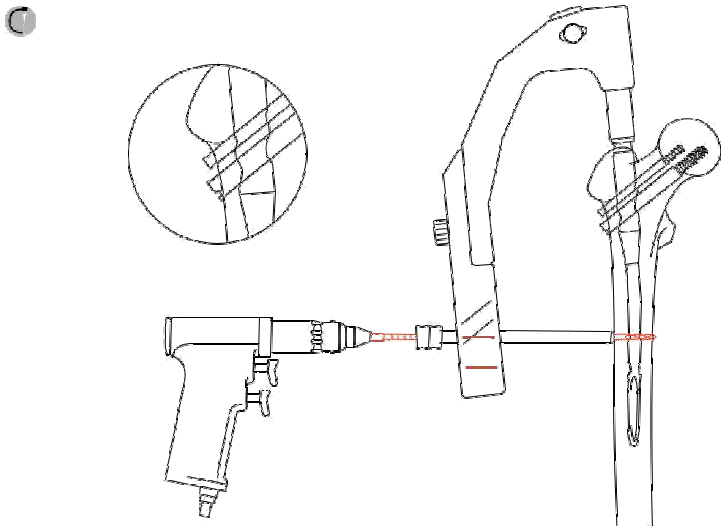
Insertion of femoral neck screw

A Measure length of femoral neck screw

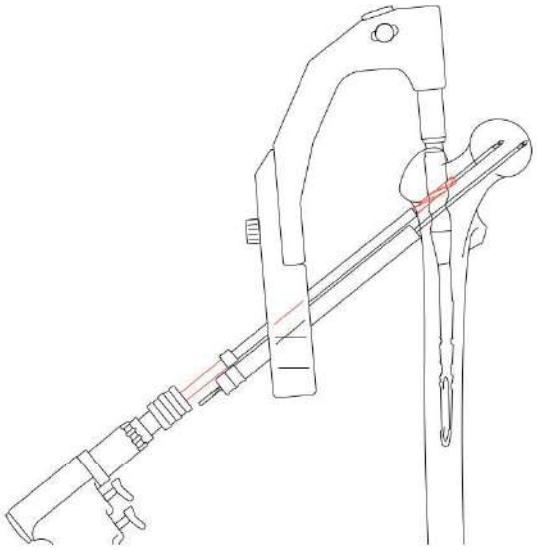


Insertion of Locking Bolt and End Cap

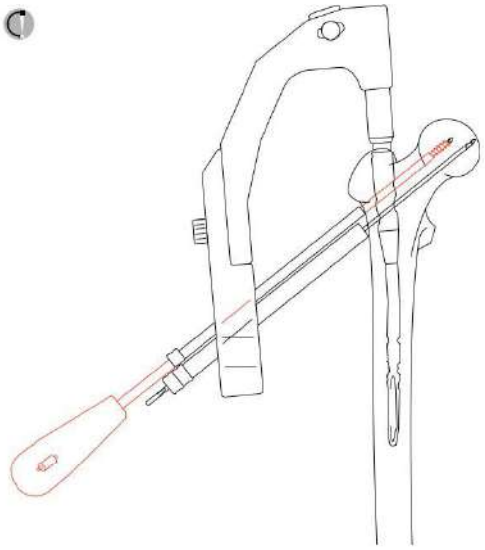
A Drill hole for distal locking



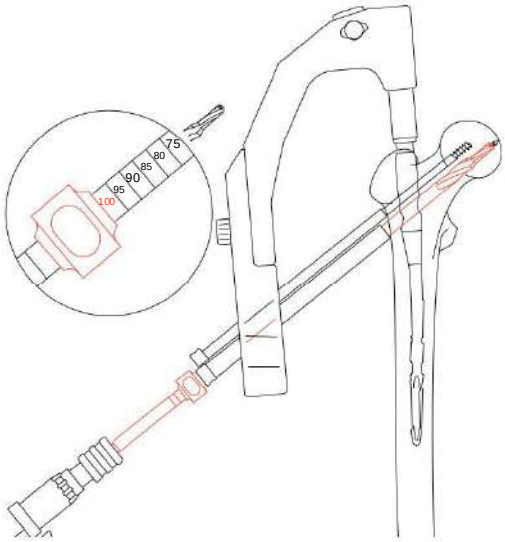
B Drill hole for hip pin



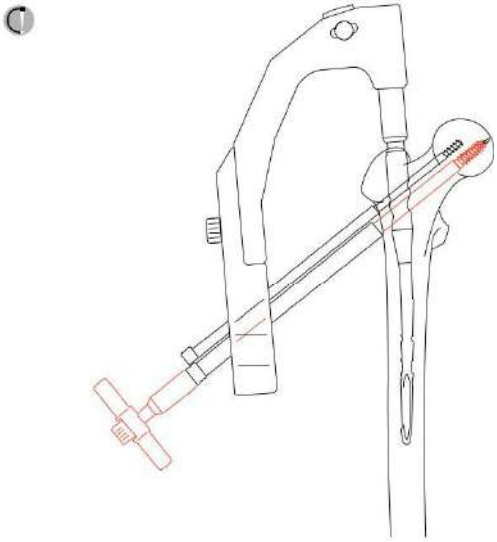
C Insertion of hip pin



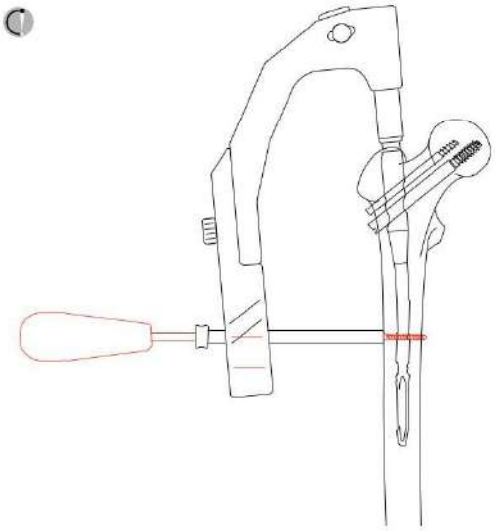
B Drill hole for femoral neck screw



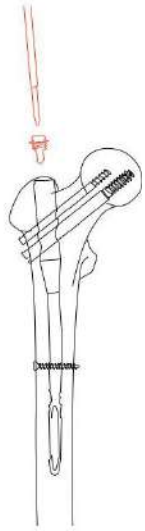
C Insertion of femoral neck screw



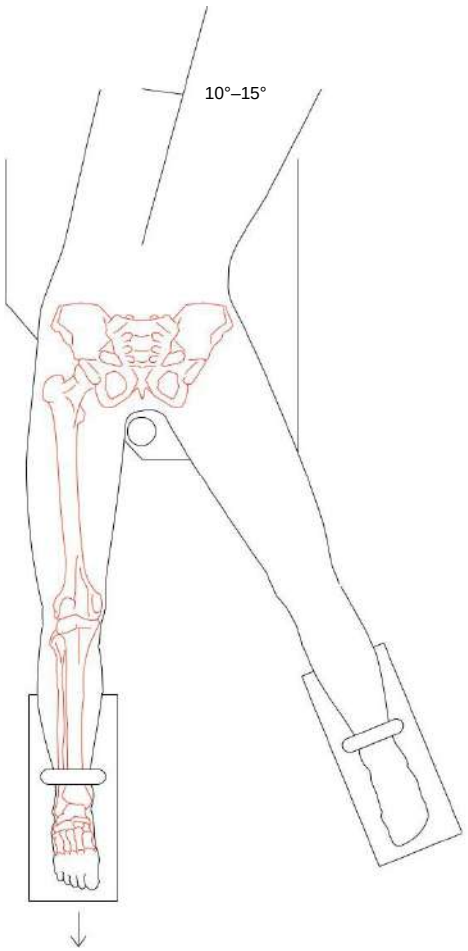
B Insertion of Locking Bolt



C Insertion of End Cap



Preparation



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 .
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).

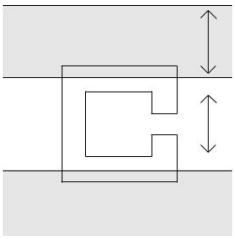
Determine CCD angle

Take an X-ray of the unaffected side preoperatively. Determine the CCD angle using a goniometer or the preoperative planning template
Standard PFN is available in 130°/135°.

Reduce fracture

If possible, carry out closed reduction of the fracture under image inten-sifier control.

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



Determine nail diameter

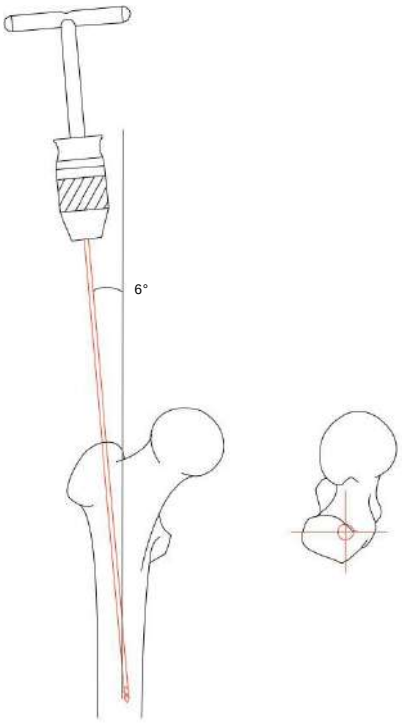
Determine the distal nail diameter by placing over the isthmus on an X-ray.

Alternative:
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.

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.

Surgical Technique for PFN



1. Determine nail insertion point and insert Guide Wire

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 2.0mm Guide Wire must be inserted laterally at an angle of 6º to the shaft. The guide wire can be inserted either manually with the

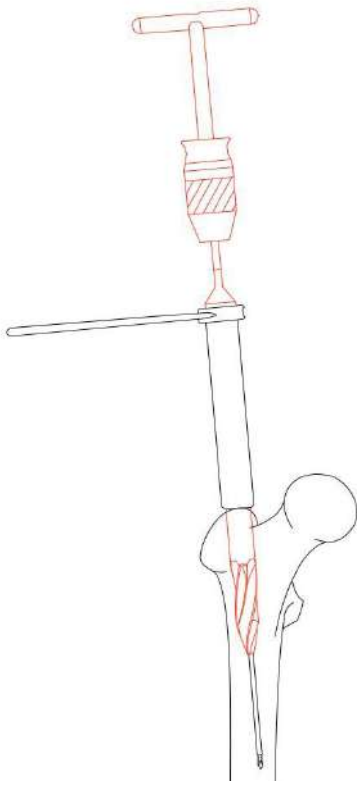
Universal Chuck with T-Handle and the quick coupling for Kirschner wires

- 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

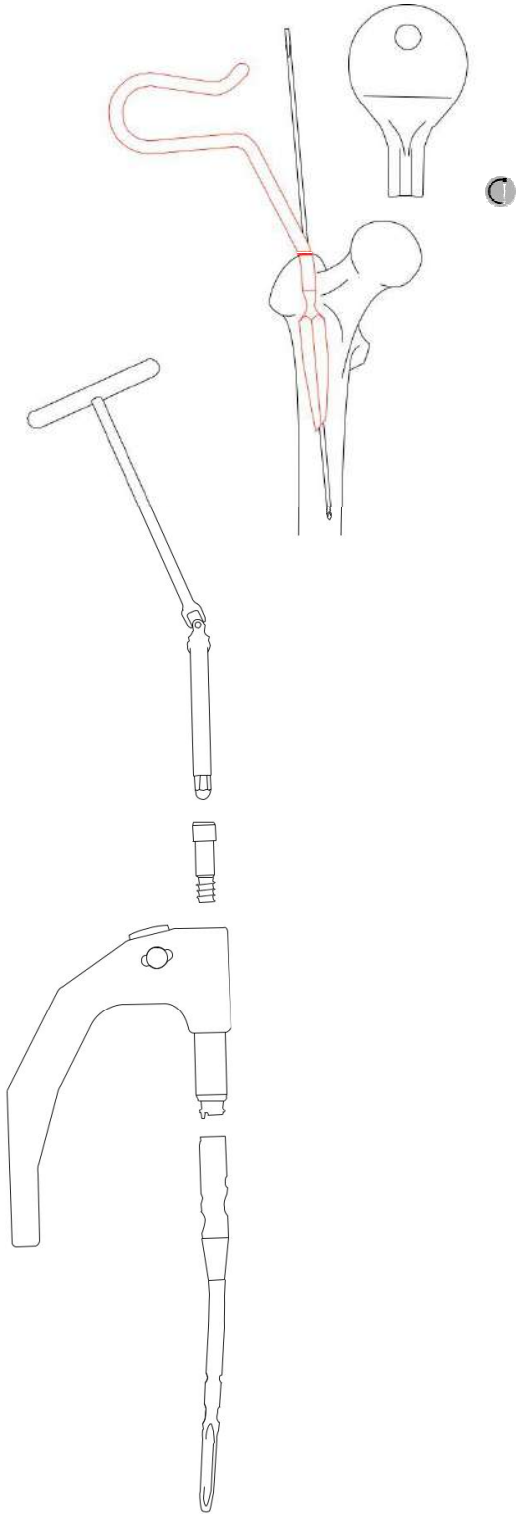
Note:

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



2. Opening of the femur

Guide the cannulated 15.0mm Drill Bit over the guide wire through the protection sleeve 10.0/12.0mm 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.

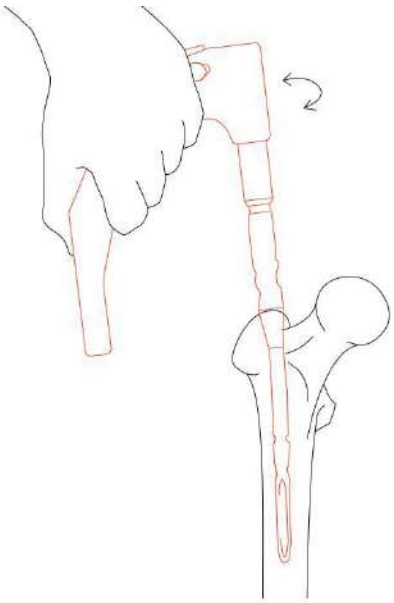


Option: opening with Reverse Awl

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.

3. 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 deter-mined 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.

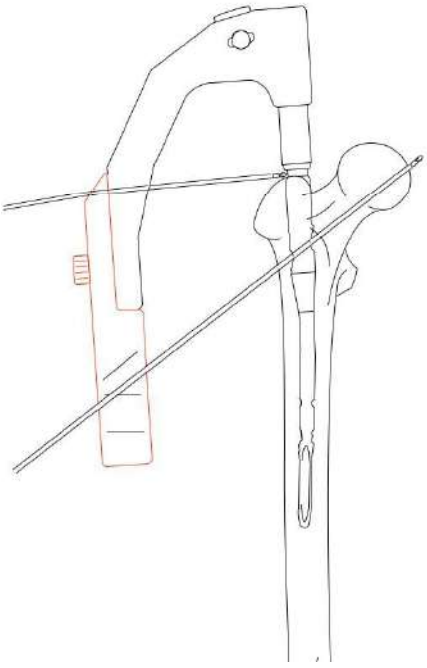


4. Insertion of Standard PFN

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.

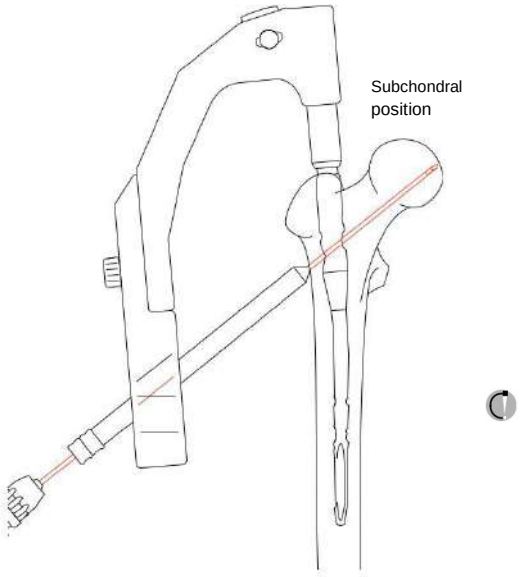
Caution:
Avoid unnecessary use of force and only hit the protection plate.
In smaller medullary canals, ream the distal part to at least 10mm.
It is important that the nail is always tightly connected to the insertion handle.



5. Insertion of femoral neck screw and hip pin

Insert these screws using the colour-coded drill sleeve systems consisting of protection sleeve, drill sleeve and trocar.
Tightly secure the appropriate Aiming Arm (130º,135°) to the insertion handle.

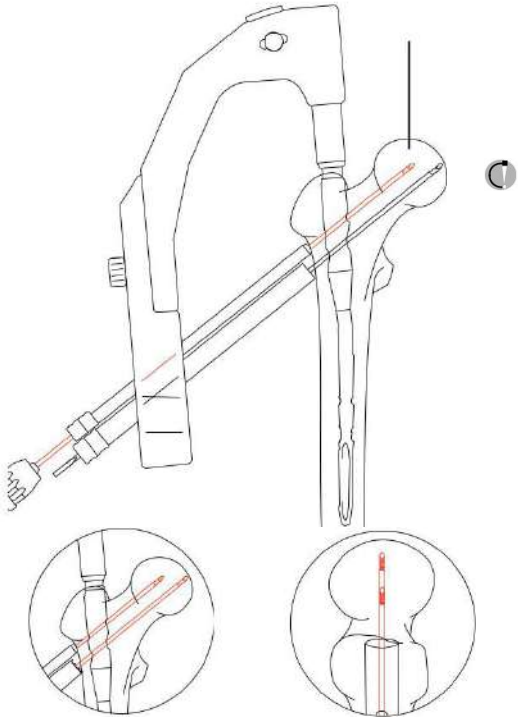
Note:
The position of the nail can be verified by placing a guide wire on the surface of the insertion handle. The position of the end of the nail can be checked by inserting a wire through the insertion handle.
To ensure the correct anteversion of the implant, an additional guide wire can be inserted ventral to the femoral neck into the femoral head.



6. 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** 2.0mm Guide Wire through the drill sleeve, check direction and position under image intensifier in 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 5mm 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 late-ral view, the wire should be positioned in the centre of the femoral neck.

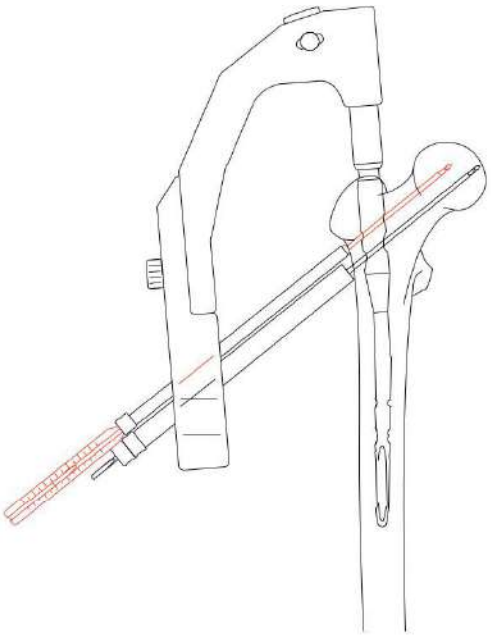
Note:
If the nail has to be repositioned, remove guide wire, protection sleeve and drill sleeve. The nail can now be repositioned by rotation, deeper insertion or partial retraction. Then reinsert the drill sleeve system and guide wire.



7. Insertion of guide wire for hip pin

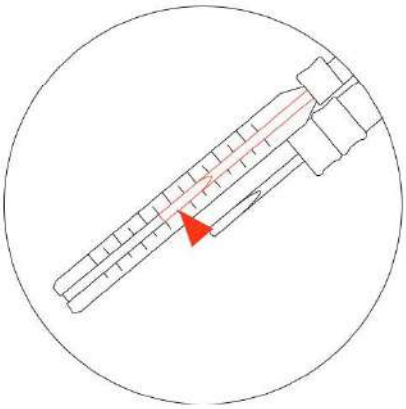
Insert the blue Drill Sleeve System through the blue drill hole on the aiming arm to the bone.
Then remove the trocar and insert a second, **new** 2.0mm guide wire through the drill sleeve into the bone. The tip of the guide wire should be positioned at least 20mm medial of the fracture line and 5mm deeper than the planned hip pin, but approximately 15–20mm less deep than the planned femoral neck screw.

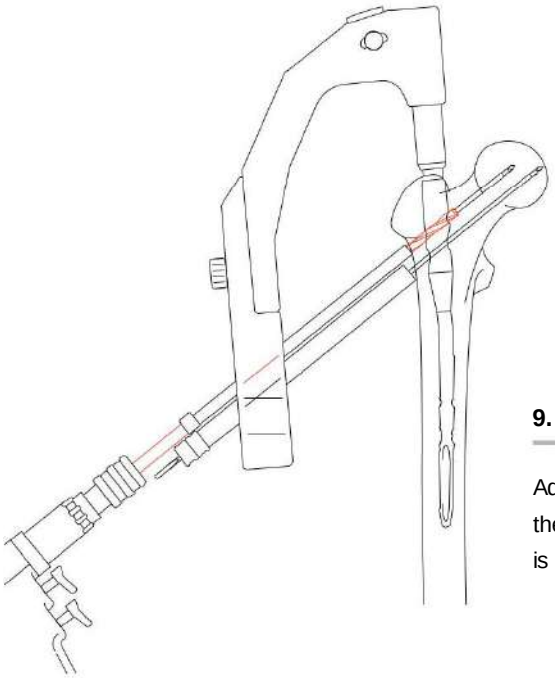
Note:
The use of a hip pin is essential to avoid rotation. As only the femoral neck screw has a load-bearing function, the hip pin should always be 15–20mm shorter than the femoral neck screw (as shown in the drawing).



8. Measure length of hip pin

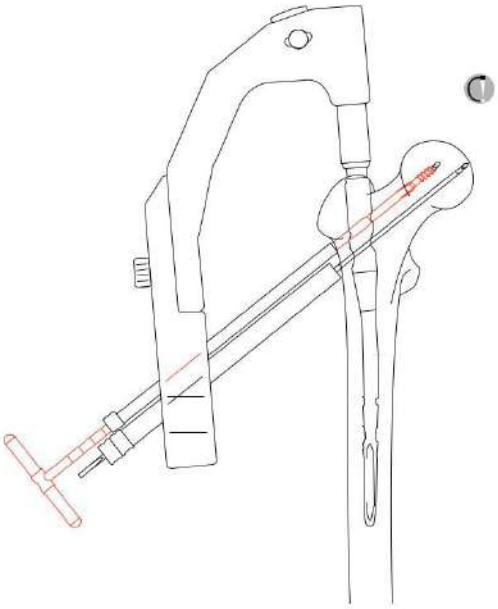
It is recommended to start with the insertion of the hip pin to prevent possible rotation of the medial fragment when inserting the femoral neck screw.
Remove the drill sleeve 6.4/2.0. Guide the Direct Measuring Device through the protection sleeve 6.4/2.0 to the bone and deter-mine the length of the 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.





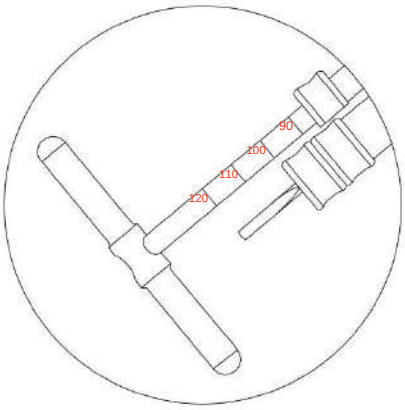
9. Drill hole for hip pin

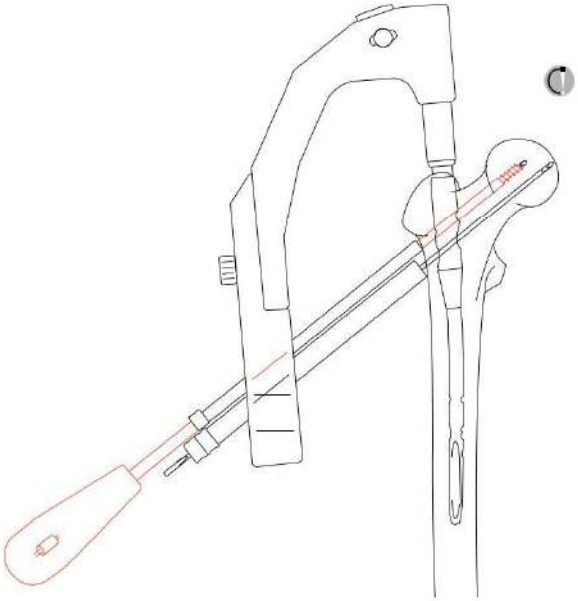
Advance the cannulated 6.4mm Drill Bit over the 2.0mm guide wire.. As the tip of the hip pin is self-tapping, usually no further drilling and tapping is needed.



10. Procedure in hard bone

In hard or young bone, further drilling and tapping with the cannulated 6.4mm Tap is recommended up to the length of the hip pin previously measured.

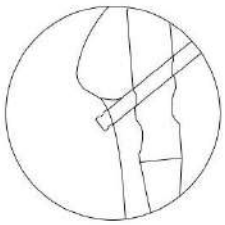


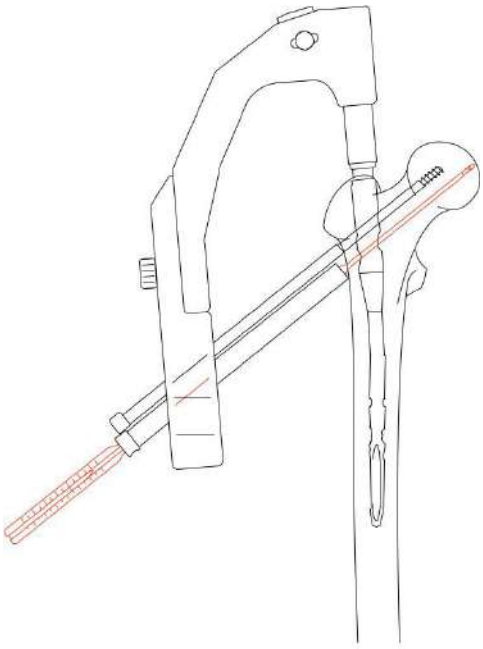


11. Insertion of hip pin

Use the cannulated Hexagonal Screwdriver to insert the select-ed hip pin over the guide wire to the stop.
Remove and discard the 2.0mm guide wire of the hip pin.

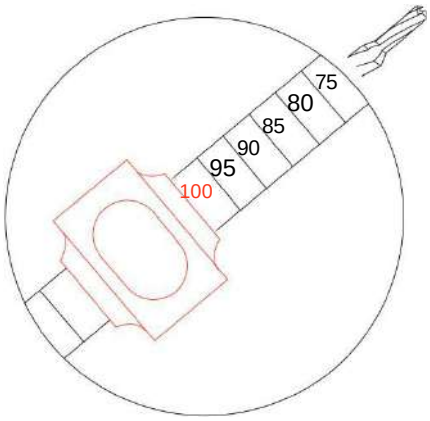
Caution:
Do not insert the hip pin with undue force. Ensure that the lateral end of the hip pin clearly protrudes from the lateral cortex. Check under image intensification that hip pin is not inserted too far.

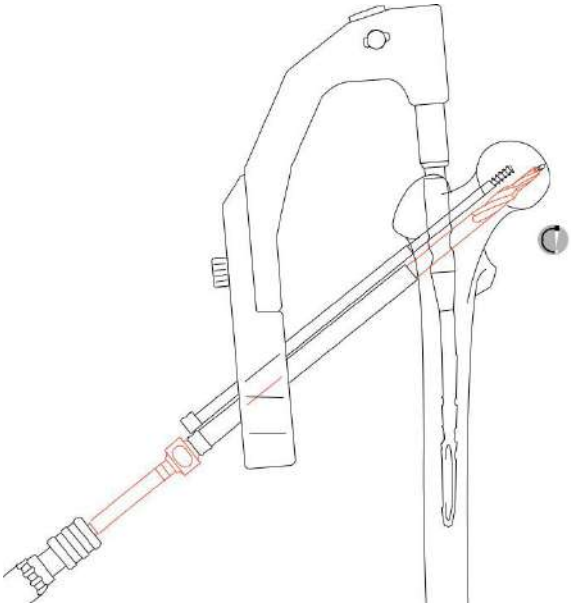




12. Measure length of femoral neck screw

Remove the pink Drill Sleeve 8.0/2.0. Guide the Direct Measuring Device over the second 2.0mm guide wire through the pink protection sleeve 8.0/2.0 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 8.0mm 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.

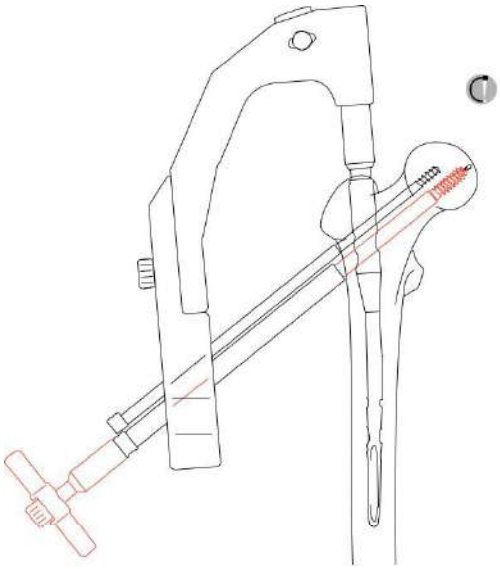




13. Drill hole for femoral neck screw

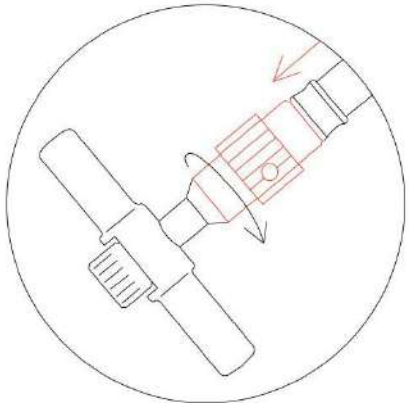
Advance the 8.0mm reamer over the 2.0mm guide wire. Drill to the stop. The fixation sleeve prevents further drilling.
Tapping is not required due to the self-tapping tip of the femoral neck screw.

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 cau-tiously complete reaming without a guide wire.



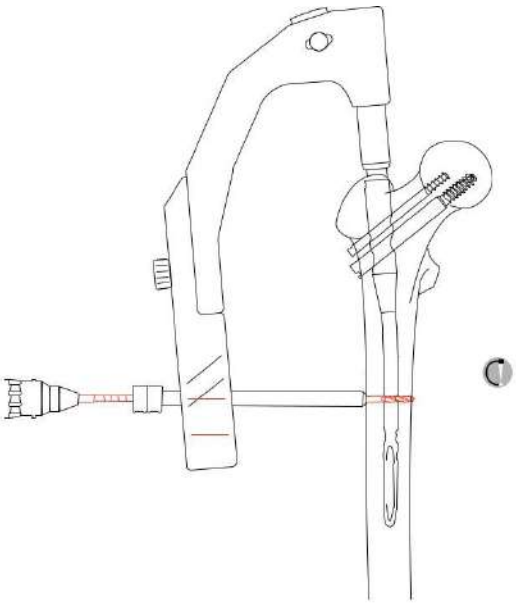
14. Insertion of femoral neck screw

Assemble the Wrench for Femoral Neck Screw and secure it tightly to the selected femoral neck screw. Insert the femoral neck screw over the 2.0mm guide wire to the stop. Remove the wrench for the femoral neck screw, if necessary using the Hexagonal Socket
Remove and discard the 2.0mm 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.



Option: Wrench for femoral neck screws with compression device

Assemble the Wrench for Femoral Neck Screw and secure it tightly to the selected femoral neck screw. The Compression Nut must be completely un-screwed in the lateral direction.
Insert the femoral neck screw over the 2.0mm guide wire to the stop.
If required, use the Compression Nut to compress the fracture with the femoral neck screw. This should be performed with great care to prevent the screw from tearing out. Do not compress in osteoporotic bone.

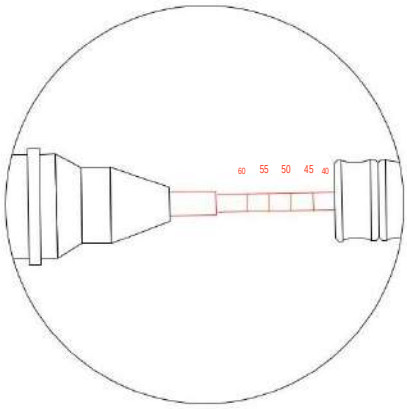


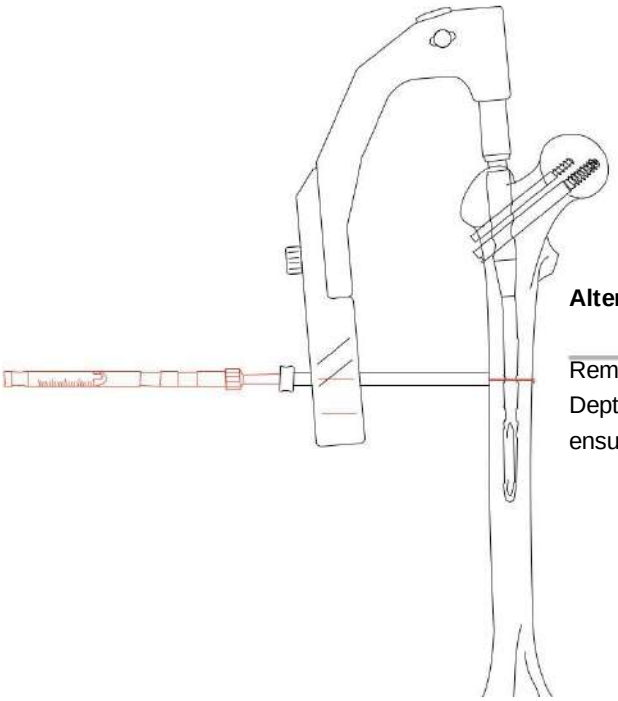
15. Drill hole for distal locking

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. Subtrochanteric 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 4.0mm Trocar and drill through both cortices using the 4.0mm Drill Bit

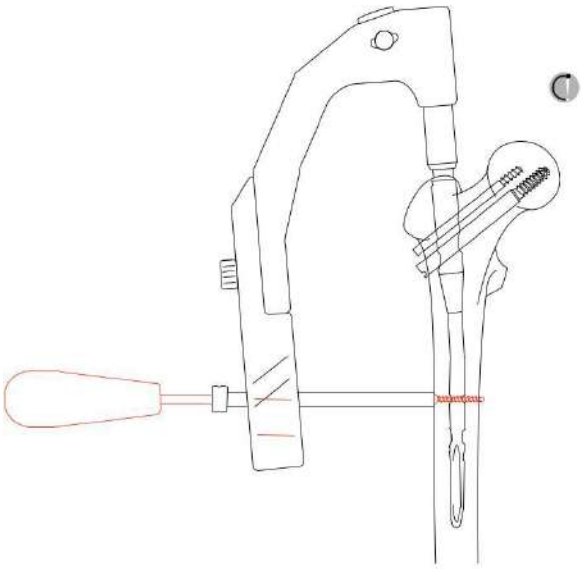
Read off the length of the required locking bolt directly from the drill marking. Ensure that the drill sleeve 4.0 has good bone contact.





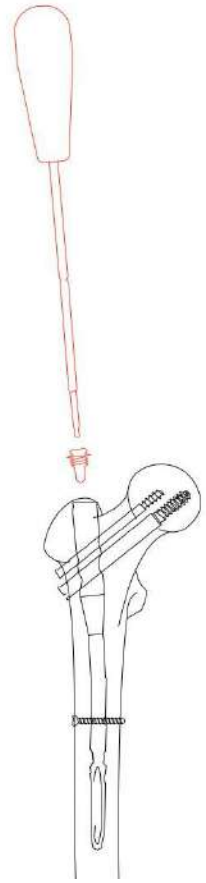
Alternative length measuring

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



16. 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



17. 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.
In order to avoid losing the end cap and to facilitate insertion, the end cap can also be inserted through the Protection Sleeve .

Proximal Femoral Nail –long PFN

Implants for long PFN

End Cap

- Proximal diameter 14.0

Self-tapping 6.4mm Hip Pin

- Lengths 60-120mm (<5mm>)
- For true rotational stability
- Featuring insertion safety stop
- Self-tapping 8.0mm Femoral Neck Screw
- Lengths 60–120mm (<5mm>)
- Featuring insertion safety stop

CCD angle 135°,

- Two different anatomically adapted nail designs for left or right leg
  Anatomical 5° ML angle
  Anatomical 1.5m radius (antecurvature)
  Cannulated nail
  Total length: 340,360,380,400,420, and 440mm

Distal 4.9mm Locking Bolt

Lengths 20-80mm (2mm Variance)

The long PFN is available in Titanium alloy and stainless steel.

SS 205	**Proximal Femoral Nail (P.F.N), (Right) (9.0 mm)**	**SS 206**	**Proximal Femoral Nail (P.F.N), (Left) (9.0 mm)**
SS 205-034	34 cm	SS 206-034	34 cm
SS 205-036	36 cm	SS 206-036	36 cm
SS 205-038	38 cm	SS 206-038	38 cm
SS 205-040	40 cm	SS 206-040	40 cm
SS 205-042	42 cm	SS 206-042	42 cm
SS 205-044	44 cm	SS 206-044	44 cm
SS 205	**Proximal Femoral Nail (P.F.N), (Right) (10.0 mm)**	**SS 206**	**Proximal Femoral Nail (P.F.N), (Left) (10.0 mm)**
SS 205-134	34 cm	SS 206-134	34 cm
SS 205-136	36 cm	SS 206-136	36 cm
SS 205-138	38 cm	SS 206-138	38 cm
SS 205-140	40 cm	SS 206-140	40 cm
SS 205-142	42 cm	SS 206-142	42 cm
SS 205-144	44 cm	SS 206-144	44 cm
SS 205	**Proximal Femoral Nail (P.F.N), (Right) (11.0 mm)**	**SS 206**	**Proximal Femoral Nail (P.F.N), (Left) (11.0 mm)**
SS 205-234	34 cm	SS 206-234	34 cm
SS 205-236	36 cm	SS 206-236	36 cm
SS 205-238	38 cm	SS 206-238	38 cm
SS 205-240	40 cm	SS 206-240	40 cm
SS 205-242	42 cm	SS 206-242	42 cm
SS 205-244	44 cm	SS 206-244	44 cm

Preparation

Detailed surgical technique

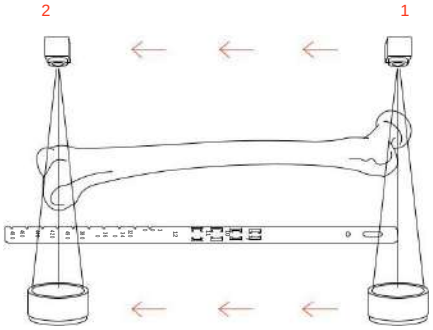
This surgical technique is based on the PFN standard surgical technique. In order to follow the correct procedure, please refer to the respective steps in the standard technique. This part only shows the steps regarding insertion and distal interlocking of the long PFN which differ from the standard technique.
Usually, the 135° nail is suitable for most indications. In some cases, however, the use of a 130° nail may be indicated.

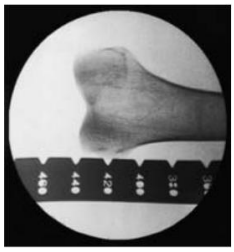
Patient positioning
Please refer to the PFN standard surgical technique.

Determine CCD angle
Please refer to the PFN standard surgical technique.

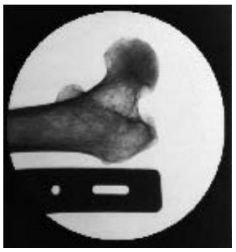
Reduce fracture
Please refer to the PFN standard surgical technique. However, the special conditions of the very different fracture types have to be considered.

Determine nail length
Position the image intensifier for an AP view of the proximal femur (1). Use long forceps to hold the Measuring Device 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 measu-ring device; this will reduce magnification errors. Adjust the device until the top is level with the tip of the greater trochanter. Mark the skin at the top of the measuring device.
Move the image intensifier to the distal femur (2), place the proximal end of the measuring device at the skin mark, and take of the distal femur. Verify fracture reduction. Read nail length directly from the measuring device 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 440mm.



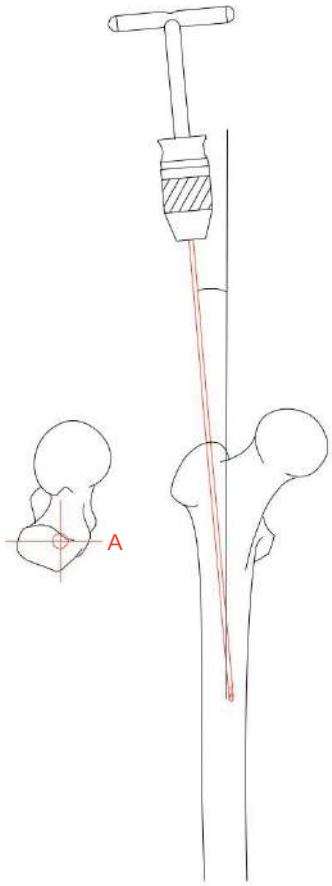


2. Read nail length



1. Position the measuring device

Surgical Technique for long PFN



Approach

Please refer to the PFN standard surgical technique.

1. Determine nail insertion point and insert guide wire

, 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 5º. This means that the 2.0mm Guide Wire must be inserted laterally at an angle of 5º to the shaft. The guide wire can be inserted either manually with the Universal Chuck with T-Handle and with the Quick Coupling for K-Wire

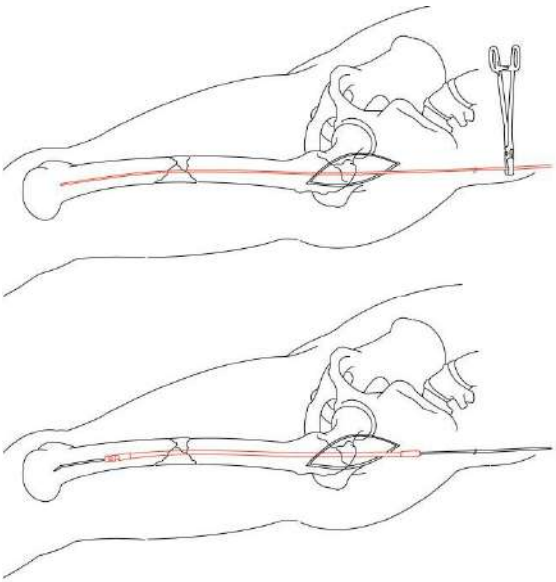
In the lateral view, place the guide wire in the centre of the medullary cavity.

2. Open femur

Guide the cannulated 14.0 Drill Bit through the Protection Sleeve over the guide wire, 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. Do not reuse the guide wire.

Directives for medullary reaming (optional technique)*



Reduction

Insert the reduction system, consisting of a T-handle a flexible Shaft a Reaming Rod and a Reduction Head into the medullary canal, and reduce the fragments under image-intensifier control.
After reduction, remove the reduction system, and leave the reaming rod in the medullary cavity.

Medullary reaming

Important:
The reaming rod is already in the medullary canal, if the reduction has been achieved by means of the reduction system.

For initial reaming, the flexible shaft is usually equipped with the 14.0mm Reamer Head

Use the highest speed and slight but uniform force to advance the reamer head in the medullary canal. Move the flexible shaft forwards and back-wards to remove the bone chips from the reamer head. This prevents jamming of the reamer head in the medullary canal.

Use sideways cutting reamer heads for the subsequent reaming steps.

Ream to the desired diameting in 0.5mm increments.

Important:
Remove the reaming rod before locking the intramedullary nail.

* For further details, see the SynReam surgical technique

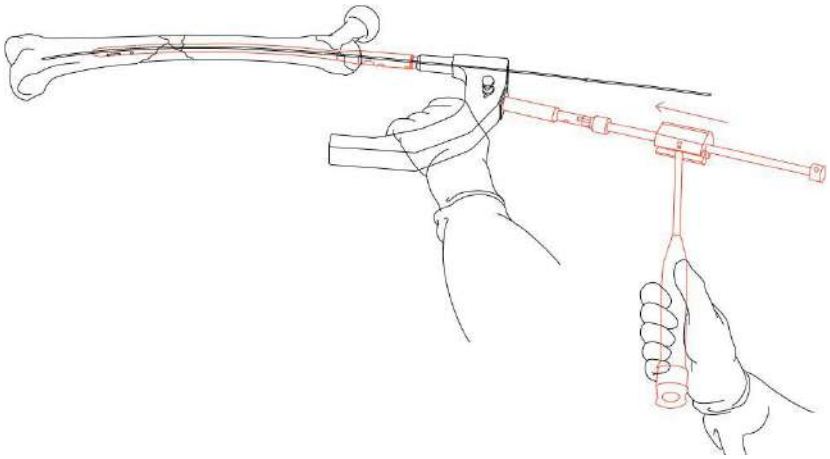
4. Assemble instruments

Please refer to the PFN standard surgical technique.

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

5. Insert long Proximal Femoral Nail

If no reaming has been performed, the guide rod may help nail insertion, but is usually not necessary.
Carefully insert the nail manually (be it over the guide rod or not) as far as possible into the femoral opening. Slight twisting hand movements help insertion. If necessary, insertion can be supported by light hammering blows. Therefore, insert the Threaded Plug into the insertion handle. Then fix the Guide Rod which is also used for nail ex-traction, through the protection plate firmly to the plug. Make sure the connection is very firm. Then use the Slotted Hammer to sup-port the insertion carefully. Remove the guide rod.



Alternative

Insertion can be supported by light hammer blows with the synthetic Hammer directly on the protection plate mounted on the insertion handle

Caution:
Avoid unnecessary use of force and only hit the hammer guide or the protection plate. Do not hit the most proximal end of the guide rod.
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.

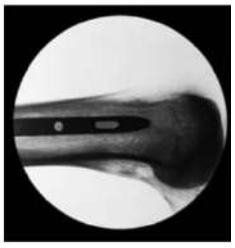
6. Insertion of hip pin and femoral neck screw

Please refer to the PFN standard surgical technique and choose the 135° Aiming Arm for the corresponding CCD-angle of the chosen nail.

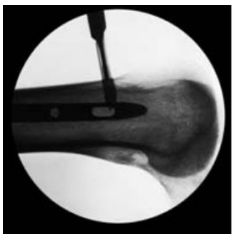
7. Distal locking

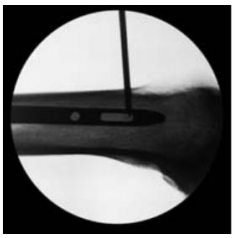
Distal locking is usually performed with two locking bolts. For static inter-locking position the caudal bolt at the proximal end of the locking slot, for dynamic interlocking position it at the distal end of the locking slot. If immediate dynamization is required, only use the caudal locking slot. For secondary dynamization insert both locking bolts and remove the static bolt at a later date.
Reconfirm reduction/alignment of the distal fragment.
Then use the Radiolucent Drive Mark II:
Align the image intensifier with the cranial hole in the nail until a perfect circle is visible in the centre of the screen. Determine the incision point on the skin and make a stab incision.

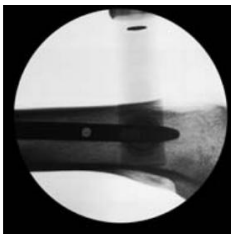

Oblique (incorrect)


Round (correct)

Under image intensification, insert the tip of the 4.0mm Drill Bit into the incision and place the bit oblique to the X-ray beam until the tip is centred in the locking hole.
Tilt the drive until the drill bit is in line with the beam and appears as a radio-opaque 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 to ensure thread engagement in the far cortex.
Insert the bolt using the large Hexagonal Screwdriver Repeat the procedure for the second distal locking bolt. For static inter-locking place the caudal locking bolt at the proximal end of the locking slot, for dynamic interlocking at the distal end to allow dynamization.


Determine incision point

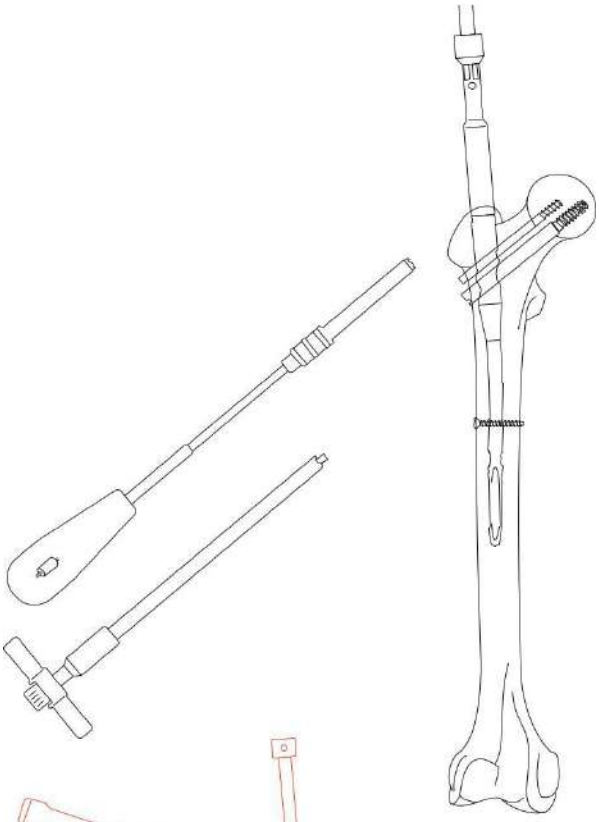

Centre drill bit in locking hole

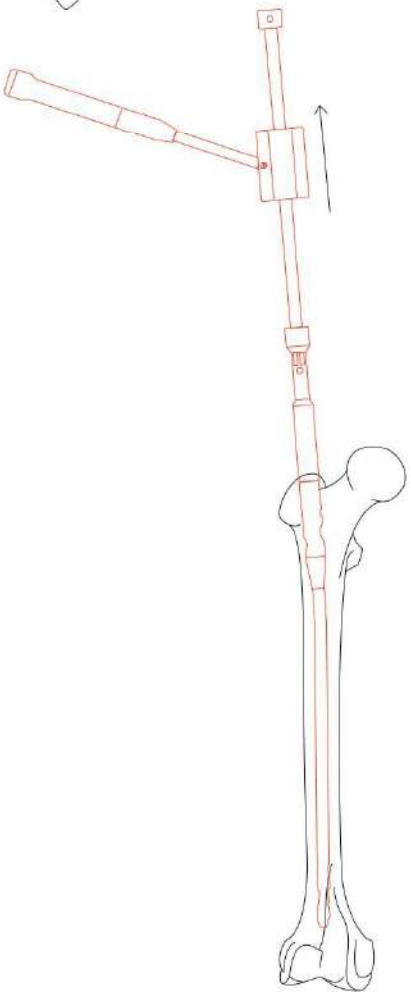

Align drill bit

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

8. Insert End Cap

Please refer to the PFN standard surgical technique.





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 2.0mm 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; Wrench may be used for this purpose. Now extract the nail with slight hammer blows.

SAMAY Surgical

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INTRODUCTION

Intramedullary nailing has become increasingly popular as a treatment for long bone fractures, and it is suitable for all fractures extending from 7-8 cm distal to the tibial plateau, to within 5.5 cm of the distal articular surface, provided that the epiphyses are closed. The MEDITECH ®Intramedullary Fixation System is a set of intramedullary nails which offers several advantages over existing systems. A major advantage of the system is the ability to insert both proximal and distal locking screws accurately and quickly without the use of X-rays, using an external mechanical targeting device. The locking screw has a smooth shank 4 mm in diameter which penetrates the distal cortex. A locking screw of this configuration is much stronger for a given diameter than a fully threaded screw. The locking holes in the nail are 4.2 mm wide. The system provides secure proximal and distal locking, ensuring maximal stability, with minimal risk of screw breakage.

INSTRUMENTS

骨螺钉螺纹扳手
Locking Screw
Extractor

骨螺钉六角扳手
Hex Screwdriver

软组织保护器
Obturator

骨螺钉代替杆
Graduated Angled
Trocar

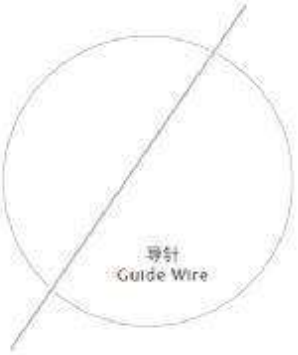
骨螺钉丝锥
Tap

锁块手轮
Clamp Locking Nut

远端支架手轮
Distal Outrigger
Locking Screw

导杆锁轮
Bar Locking Screw

导针替换管
Guide Wire Exchange
Tube



导针
Guide Wire

卡子
U-shaped Stabilizing
Spacer

测深尺
Depth Gauge


拔出器手柄
Screw Adapter


护皮板
Skin Protector


打入(拔出)器
Sliding Hammer


手柄
Nail Support Handle


快接手柄
Quick Connect Handle


髓腔开孔器
Pointed Awl


吊紧螺栓
Locking Rod


近端支架
Proximal Outrigger


远端支架
Distal Outrigger


导杆
Guide Bar


定位杆
Stabilizing Rod


定位杆手钻
T-handled Reamer


定位杆
Stabilizing Rod
球头导针
Guide Wire
with Olive
导针替换管
Guide Wire
Exchange Tube
送针器
Gripper
扩髓钻头
Flexible Reamer Head
软扩髓钻杆
Flexible Shaft

IMPLANTS


胫骨髓内钉,空心
(不锈钢)
Tibial Nail,
Cannulated, SS
胫骨髓内钉,实心
(不锈钢)
Tibial Nail,
Solid, SS
胫骨髓内钉,实心
(钛合金)
Tibial Nail,
Solid, Ti

锁钉(不锈钢)
Locking Screw, SS

锁钉(钛合金)
Locking Screw, Ti

封帽(不锈钢)
End Cap, SS

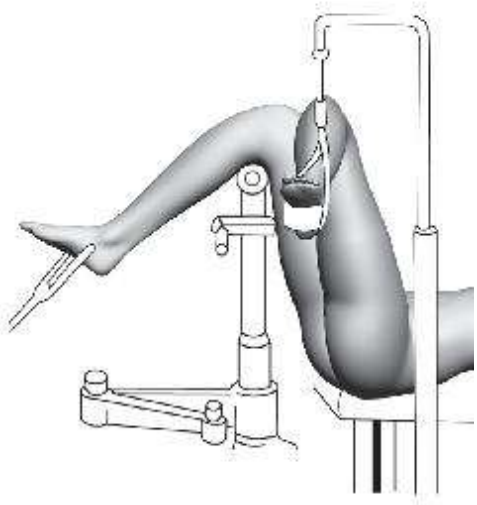
封帽(钛合金)
End Cap, Ti

PRE-OPERATIVE ESTIMATION OF NAIL AND LOCKING SCREW SIZE:

The surgeon should be able to gain a good estimate of the required length pre-operatively, by direct measurement of the length of the tibia from the plateau to the medial malleolus, if necessary, using the uninjured leg. By looking at the width of the medullary canal on the radiograph, and from the knowledge of the weight of the patient and the severity of the fracture, the surgeon will be able to gauge the likely diameter of the nail, and whether to use a reamed or an unreamed nail. It should be noted that the X-ray film has magnification of 8% or 15%. A larger nail is indicated in severely comminuted diaphyseal fractures and in proximal third fractures to provide extra stability. In general,the size of nail chosen will depend on the size of the bone, and the amount of reaming, if any, that the surgeon is prepared to accept.

PREPARATION OF THE PATIENT

Position the patient supine on a radiolucent operating table. Ensure that the knee of the injured leg can be flexed at least 90°and x-ray visualization of the entire tibia is possible in both the AP and lateral views. Temporary reduction and stabilization can be accomplished by manual pressure at the fracture site, or by application of a sterile tourniquet or elastic bandage around the fracture.Alternatively, reduction can be achieved by skeletal traction with Steinmann-type pin inserted through the os calcis. At the surgeon's discretion, the procedure can be performed on a fracture table with the leg placed in traction.

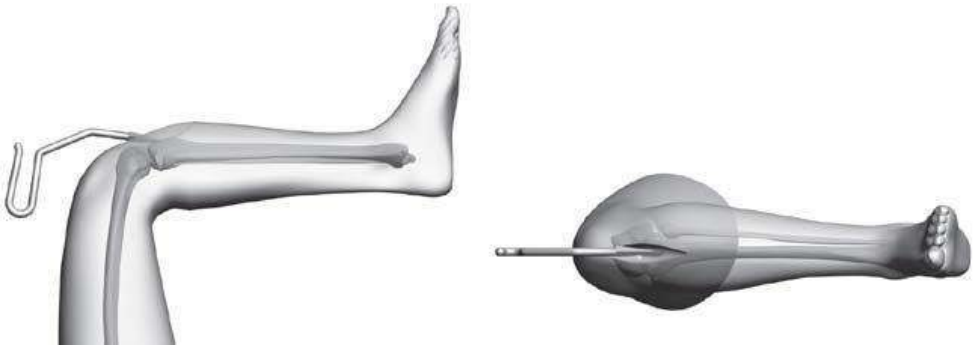


INSERTION SITE

The entry point for the nail is in line with the medullary canal in the AP view, and is at the anterior edge of the tibial plateau. The location of the entry point in relation to the tibial tubercle varies with patient anatomy. Make a longitudinal incision over the midline of the tubercle, extending proximally.Retract the patellar tendon laterally, or split the tendon, depending on surgeon preference and patient anatomy.

The tip of the Pointed Awl is placed at the entry point and the Image Intensifier used to confirm that this is centered over the canal. If it is not, it is adjusted until it is satisfactory, checking the position of the tip of the awl in the medial-lateral plane.

The awl is then advanced with a rotational action towards the medullary cavity, keeping the straight part of the handle parallel with the tibial diaphysis,so that the tip of the awl is pointing directly down the tibial shaft.



INSERTION SITE (CONTINUED)

The awl is removed, and at this point it is useful to confirm that the medullary canal has been opened, using the 7 mm Rigid Reamer, which is gently pushed down into the medullary canal. The introduction of the Rigid Reamer should be stopped as soon as resistance is felt. With the Rigid Reamer in place, the Image Intensifier should now be used to confirm alignment in both planes. The entry portal is opened to 9 mm with the larger Rigid Reamers, and is now ready for the insertion of an unreamed nail, or for a guide wire prior to reaming, as described below.

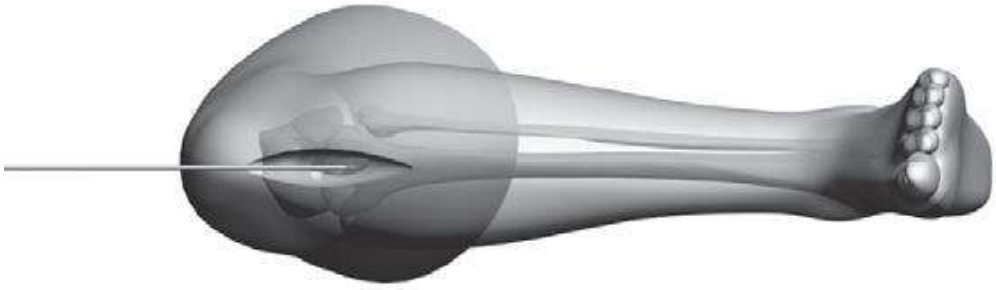
REAMING PROCEDURE

If an unreamed nail is to be inserted, ignore the following section on reaming, and proceed to the section on Nail Insertion-Unreamed Nail.

Guide Wire Insertion

Throughout this procedure, care should be taken to retract the patellar tendon away from the operating field, to avoid damaging it and to use the **Skin Protector** to avoid bruising the articular

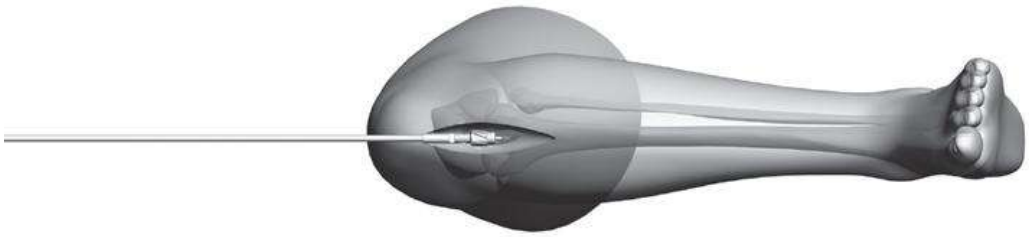
surface of the patella, or the overlying skin. The **Guide Wire with Olive** is now inserted through the hole and passed along and through the proximal fragment. Once the proximal end of the fracture line has been reached, the Guide Wire is manipulated in such a way that it reaches the distal fragment. A bend in the tip may be necessary to allow the surgeon to control the direction of
insertion by turning the wire. In difficult cases, it is useful to attach a **Gripper** on to the proximal end of the wire for additional control. Guide wire insertion must be carried out under image intensification in two planes. In mid-shaft fractures, the path of the Guide Wire is dictated by the contour of the medullary canal, and this may help to prevent valgus or varus displacement of the distal fragment. The Guide Wire is inserted until its tip sits 0.5-1 cm proximal to the ankle joint, care being taken to ensure that it is exactly in the midline. The Gripper should be removed leaving the Guide Wire.



REAMING PROCEDURE (CONTINUED)

The medullary canal is now reamed by passing reamer over the Guide Wire, always starting with the 7.5mm reamer. Reaming should be continued in 0.5 mm increments before the medullary canal is reamed to 9mm. After that, the reaming should be continued in 1.0mm increments, up to a width 1-2mm greater than the nail diameter, 1 mm normally being sufficient. The Skin Protector should be used proximally. Reaming past the isthmus is generally sufficient except in the case of a distal fracture, where reaming should be extended beyond the fracture line.

Steady pressure should be exerted while reaming and a check should be made that the reamer is advancing at all times. Excessive pressure, or a reamer that is not advancing, may indicate that the reaming head has become clogged with bone debris. It is very important in these cases to remove the reamer and clean the head. In young patients with hard bone this may be necessary more than once. If the reamer will not pass easily in spite of cleaning the head, it should be removed, and the previous size inserted, and passed slowly up and down the canal twice. A check should also be made to ensure that the reaming heads are being used in the correct order. A reamer that is not
advancing for any reason may cause significant thermal damage to bone and soft tissues. The reamer may jam if the power is turned off while it is in the canal, and this should be avoided.

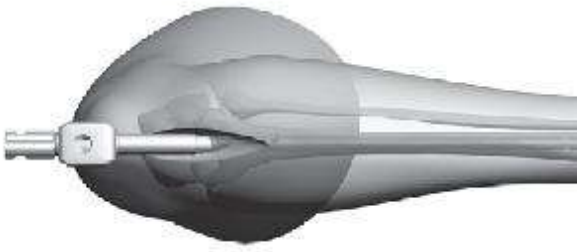


NAIL INSERTION (CONTINUED)

The nail must be rotated until it seats into the correct position and the Locking Rod is then firmly tightened into the nail, completing this with the **SW 5 Wrench**. Before the nail is inserted, it is important to check alignment of the distal and proximal holes in the nail and the **Guide Bar.** In order to do this, the Guide Bar is mounted on to the handle following the procedures described below under “Distal Locking”and “Proximal Locking”pages.

The nail is now manually inserted over the Guide Wire into the medullary canal as far as possible,under image intensification. The nail is advanced into the distal fragment until the step on the nail support is flush with the surface of the bone. This indicates that the nail has been inserted to the correct depth. Ideally, the nail should be inserted by hand, but gentle tapping may be necessary.

Note:Remove the Guide wire prior to drilling holes and insert the Locking Screws.

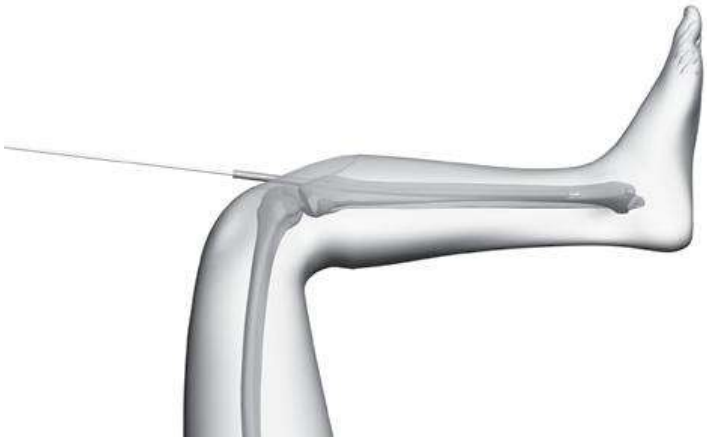


NAIL INSERTION

Reamed Nail

The plastic **Guide Wire Exchange Tube** is inserted over the Guide Wire with Olive,

so that it is well across the fracture site. Holding the tube in place, the Guide Wire is now removed, and the Guide Wire is inserted. After confirming that the tip of the **Guide Wire** is in the correct position, the plastic tube is removed for insertion of the cannulated nail.



For solid nails, directly insert the nail following below description after removing the Guide Wire withOlive.

A nail of correct diameter and length is now selected. The **Locking Rod** is inserted into the back of the **Nail Support Handle** and the chosen nail into the nail support

The **Sliding Hammer** maybe attached to the end of the nail Locking Rod, and it must be tightened fully to avoid damage to the thread. The nail can then be inserted into the correct position by gentle hammering. Ideally, the proximal end of the nail is recessed in the bone by 10-15 mm. If the nail will not advance, it should be removed, after replacing the Guide Wire, and the bone reamed an additional 1.0 mm. If this is unacceptable, a smaller diameter nail should be inserted.

Note: After the Sliding Hammer has been removed, a check should be made to ensure that the Locking Rod is tightened firmly.

Unreamed Nail

It is always preferable to use a 9 mm nail if possible. The 8 mm or 9 mm nail is locked firmly to the Nail Support Handle with the Locking Rod as for the reamed nail. It is then inserted through the entry portal into the medullary canal, and advanced manually as far as possible, using X-ray control.It will normally be necessary to attach the Sliding Hammer, as described above, to complete the insertion, hammering as gently as possible.

Care should be taken to ensure that the nail remains parallel to the tibial diaphysis, to avoid perforation of the cortex. If the nail will not pass in spite of hammering, the situation should be

carefully reviewed with the Image Intensifier. The tip of the nail may be striking the posterior cortex.In this case the nail should be removed by reverse hammering, and the direction of the entry portal adjusted. If the nail will not pass, but the direction seems to be correct, it should again be removed,and consideration given to using a smaller nail, or to reaming.

At the end of insertion, the fracture site should be checked by X-ray to see whether nail insertion has caused any distraction of the fragments. Distraction at the fracture site for any length of time may be associated with compartment syndrome, and must be avoided. If at all possible, any distraction should be corrected now by compression between heel and knee. If full correction is not achieved at this time, it can be affected following distal locking, which in this case must be done first.It is also important at this stage to check for axial reduction in the sagittal and coronal (frontal)planes.

Note: Both reamed and unreamed nails can be advanced by gentle rotational movements until the bend in the nail reaches the surface of the bone. After this the nail must be advanced without

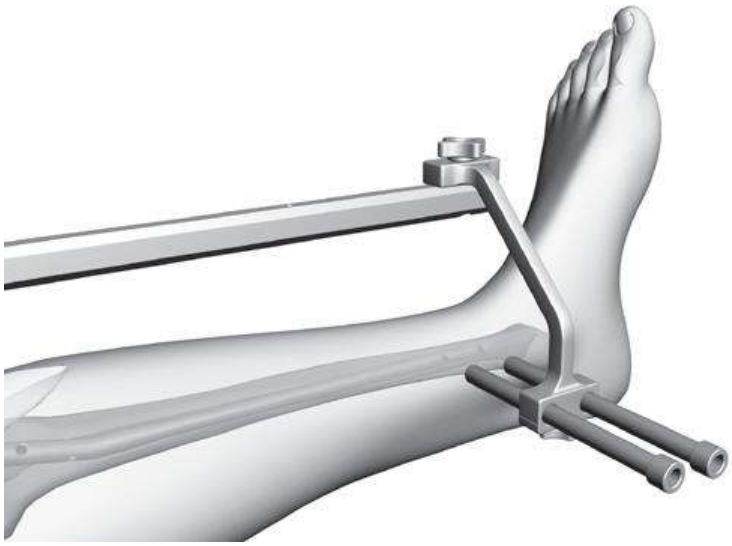
rotation by pushing or hammering.

DISTAL LOCKING

It is generally recommended that distal locking is performed first, because it is potentially more difficult. In very proximal or unstable fractures, however, it may be preferable to carryout proximal locking first.

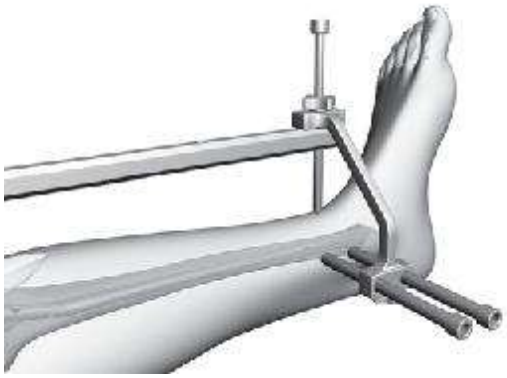
The Guide Bar is introduced into the handle, moved downwards until the number corresponding to the nail length is at the level of the front of the handle, and locked firmly into place. Note that there is a depression for the tip of the **Bar Locking Screw** corresponding to each nail length. A retaining ball in the handle makes finding the correct position of the Guide Bar easily. The distal locking screws are inserted in the frontal plane, normally from the medial side. On rare occasions, because of skin damage medially, or because of the configuration of a distal fracture, the surgeon may wish to insert the screws from the lateral side. In this case the **Distal Outrigger** is placed on the lateral side, and the nail is rotated so that the locking screws will pass anterior to the fibula. The procedure for distal locking is then identical to that for the more usual medial approach.

The Distal Outrigger is mounted on the Guide Bar so that it lies on the correct side of the tibia, and the Screw Guides are inserted into the Outrigger, but no incision is made as yet. The system is first stabilized in exact alignment, utilizing the Stabilizing Rod.

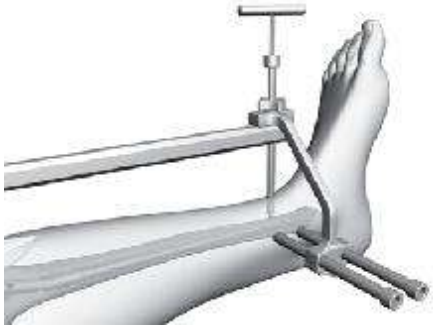


A **Drill Guide** (f7/f4) is inserted into the holes in the **Distal Outrigger Locking Screw** . An incision is made in the skin directly beneath it, and the anterior tibial cortex exposed by blunt dissection using the **Obturator**, taking care to deflect the tendon of Tibialis Anterior laterally to avoid damage to it or to the neurovascular

bundle. The Drill Guide (φ7/φ4) is advanced until its tip is engaged in the tibia,and stabilized on the center of the tibial crest. A 4 mm **Drill Bit** is now used to drill the anterior cortex only. The Drill Bit is removed. A **Pin**(φ4) can also be used to drill a recess on the tibial cortex before using Drill Bit to increase its stability.

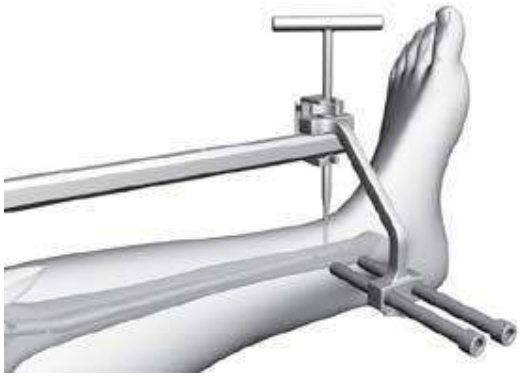


The square ended 4mm **T-handled Reamer** is passed down the drill guide, and used to complete the hole down to the nail, and to remove intervening debris. It should be possible to feel and hear
the tip of the reamer touching the nail. The T-handled Reamer and Drill Guide are now removed,and replaced by the Stabilizing Rod, which is inserted through the anterior cortex down to the nail, again gently tapping it on to the nail to confirm that there is no intervening debris.

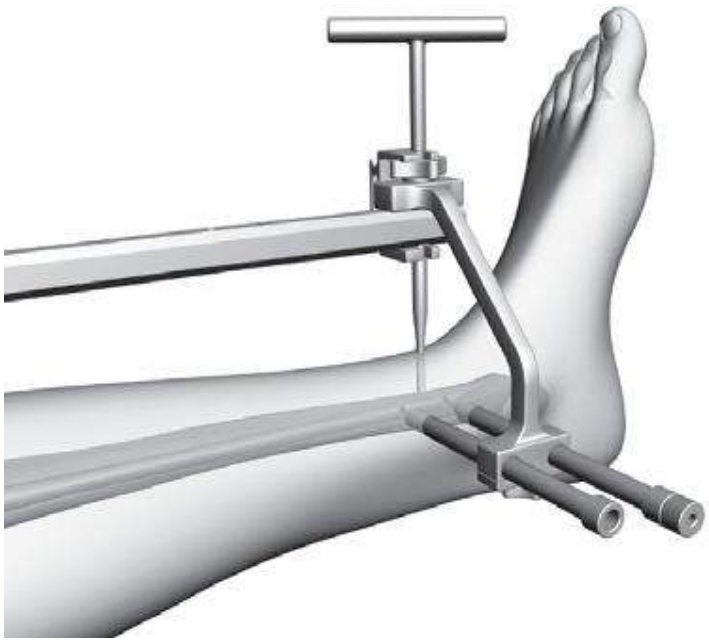


The Stabilizing Rod must now be fixed in an exact position according to the diameter of the nail, and this is achieved by clipping the appropriate **U-Shaped Stabilizing Spacer** on to the Guide Bar, so that its forks engage the two recesses in the Stabilizing Rod. The three spacers are each calibrated for two nail diameters, with a figure from 8 to 13 engraved on each side. A spacer should be positioned so that the correct nail diameter is visible on the upper surface, facing towards the surgeon.

The assistant now exerts gentle pressure on the T-handle of the Stabilizing Rod, so that its tip is pressed against the nail. This ensures that the distance between nail and Guide Bar is constant,allows for any deformation of the nail in the sagittal plane, and maintains the alignment for the distal targeting. It also stabilizes the Guide Bar and Outrigger, so that the surgeon has a secure platform for drilling the distal holes. It is possible, if the assistant presses too hard, for the tip of the Stabilizing Rod to be pushed past the nail. Normally, gentle pressure only is required, and the assistant should be able to feel the contact between the tip of the Stabilizing Rod and the nail at all times. On occasion, a gentle UPWARD or DOWNWARD pressure may be necessary to ensure that the tip of the Stabilizing Rod remains in contact with the anterior portion of the nail.



An incision is now made beneath each Screw Guide, and the cortex exposed in each incision by blunt dissection,taking care to avoid entrapment of, or damage to, the neurovascular structures. Similarly, if the approach is from the lateral side, the surgeon must ensure that the tendons and vessels are not damaged during the locking procedure, by careful soft tissue dissection down to the bone. The Screw Guides are then advanced until they are in contact with the cortex, and the Clamp Locking Nut on the Outrigger tightened to hold them firmly in place.

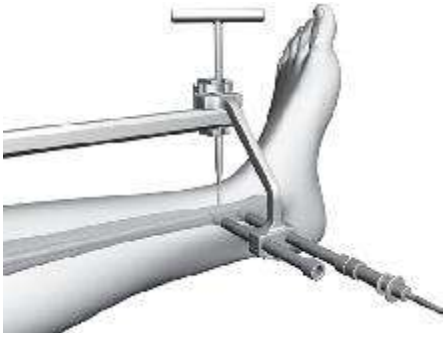


As with all distal locking procedures, the surgeon's drilling technique is vital to the success of the procedure. It is important that the drill is held securely in line with the **Drill Guide** (φ8/φ4), avoiding any bending of the drill bit. Excessive force should be avoided, so that the surgeon can "feel" the drill passing through the bone and the nail. If the drill has a pistol grip, it is very important that the force applied during drilling is axial to the drill bit, and directly in line with it. Pressing on the handle of this type of drill causes a bending force to be transmitted to the drill bit, and this may be sufficient for it to miss the holes in the nail.

The assistant maintains constant contact between the tip of the Stabilizing Rod and the nail throughout this procedure, if necessary, by applying gentle pressure. The Drill Guide(φ8/φ4) is inserted into one of the Screw Guides and gently tapped to engage the tip in the cortex. The surgeon continues to hold the the Drill Guide (φ8/φ4) with one hand until the first cortex has been drilled.

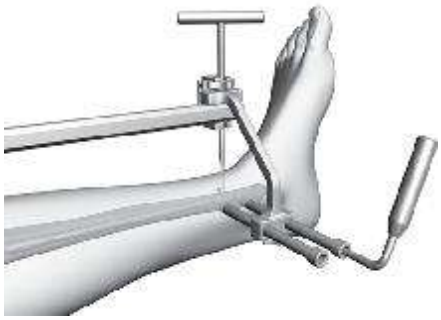
The **Drill Stop** is attached to the Drill Bit at the proximal end. The Drill Bit is introduced into the Drill Guide (φ8/φ4), down to the bone, before the drill is started, and gently pressed to engage the tip in the cortex.

The surgeon now drills steadily through the near cortex, and stops when the second cortex is reached. The Drill Stop is moved down until it is 7-10 mm above the top of the Drill Guide (φ8/φ4),and locked into place. This represents the thickness of the second cortex. Drilling now continuesthrough the second cortex. The Drill Stop prevents damage to the tissues beyond the bone, and also provides a method of estimating the correct length of the locking screw.



DISTAL LOCKING (CONTINUED)

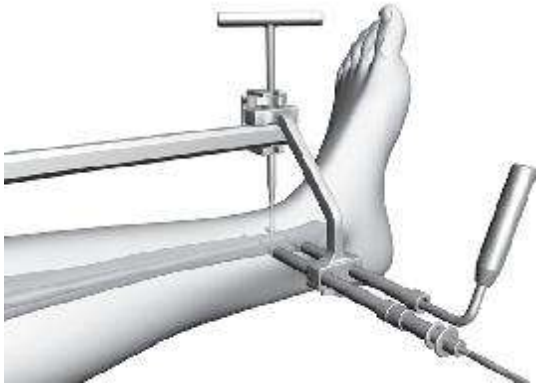
The Drill Bit is removed with the Drill Guide (φ8/φ4). The **Graduated Angled Trocar** is now inserted into the Screw Guide, so that it passes through the nail, and engages the far cortex. This trocar should now have stabilized the position of the Guide Bar and Outrigger in relation to the nail, and its position can be confirmed by manipulation or with the Image Intensifier. Now that Screw Guide alignment is maintained by this trocar, the assistant may release the T-handle of the Stabilizing Rod.



The appropriate locking screw length, from the top of the screw head to its tip, is determined by measuring the amount of drill bit protruding from the Drill Guide (φ8/φ4), and then add 5mm to it. The tapered tip of the Drill Bit should be ignored in this measurement. A screw of the correct length is reserved. An alternative method of screw measurement using the **Depth Gauge** is described below.

The Drill Stop is now replaced at the proximal end of the Drill Bit. The second

locking hole is now drilled, using exactly the same technique. The length of the second locking screw is determined.

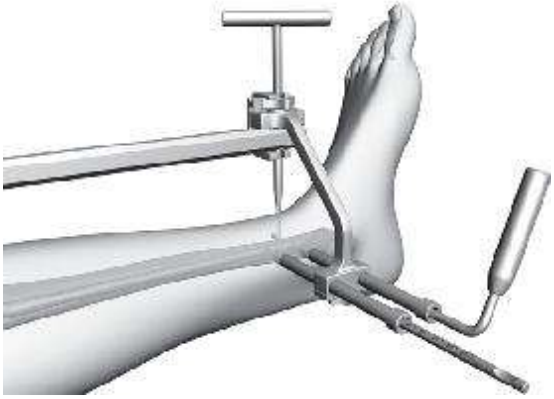


The **Tap** is inserted into the Screw Guide to tap the proximal cortex. There have three circular marks on the Screw Tap which indicate the depth of tapping are 6, 8, 10mm according to the length of a locking screw's thread. The Screw Tap is removed. A locking screw of correct length is now inserted into the second Screw Guide, and pushed through the bone with the **Hex Screwdriver**, until its thread engages the cortex. Note that there is a circular mark on the Screwdriver Shaft. This mark will be 6-10 mm above the top of the Screw Guide when the locking screw has been pushed in sufficiently. There is no point in turning the Screwdriver until this position is reached, because there will be no thread in contact with the bone. The Screwdriver is now turned steadily clockwise,exerting gentle pressure, until the mark on the shaft of the Screwdriver reaches the top of the Screw Guide. One more complete turn should then be made to tighten the screw fully. It is important not to continue turning after this position is reached, because the thread in the bone may be stripped.

The assistant again holds the Stabilizing Rod, and the Graduated Angled Trocar is removed from the first screw guide. The same technique is followed for insertion of the second distal locking screw,after which both Screw Guides are removed by loosening the Clamp Locking Nut. A check should now be carried out with the Image Intensifier or radiograph to confirm that both locking screws have passed through the nail and to confirm that the reduction has been maintained. The Distal Outrigger and the Stabilizing Rod are now removed.

ALTERNATIVE METHOD OF ESTIMATING LOCKINGSCREW LENGTH USING THE DEPTH GAUGE

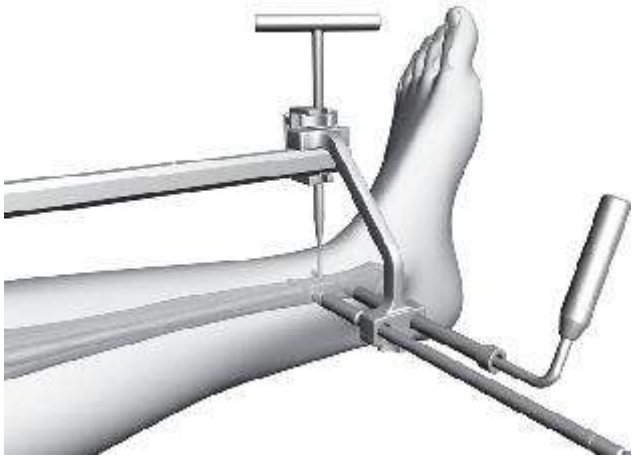
If there is any doubt about the correct locking screw length, either in respect of the measurement obtained after drilling, or because the surgeon omitted this step, the locking screw Depth Gauge may be used as follows: the surgeon should first check that the screw guide is positioned so that it is touching the bone. The Depth Gauge cover is then unscrewed and removed. The hooked end is inserted down the Screw Guide and through the bone. It is then drawn back so that the hook engages the outer surface of the far cortex. The correct length of screw can now be read at the top of the Screw Guide. This Depth Gauge is only suitable for use with ORTHMED® Tibial and Femoral Nails, since its accuracy depends on a fixed length of Screw Guide.



LOCKING SCREW REPLACEMENT

If a locking screw should need replacing for any reason during the course of the

operation, the **Locking Screw Extractor** should be used, as described in the section on Nail Removal at the end of this manual.



CHECK FOR FRACTURE DISTRACTION

Before proximal locking is carried out, the fracture should be screened to check for any distraction. If this is present, the Sliding Hammer can be reattached to the Locking Rod as described previously.The fracture gap can then be closed by gentle reverse hammering, after which the hammer is removed. It is very important to avoid completing the locking of the nail with the fracture distracted.There is an association between fracture distraction, and delayed union or compartment syndrome.

PROXIMAL LOCKING

The Guide Bar Locking Screw is loosened, and the bar moved until the Zero mark is level with the front surface of the handle, where it is locked into position. The **Proximal Outrigger** is mounted on the bar, and two Screw Guides inserted into the guide seats to locate the sites for the incisions.Before making the incisions, the surgeon should carry out a final check for reduction of the fracture,remembering the possibility of distraction. An incision is made beneath each Screw Guide, and the tibial cortex exposed in each case by blunt dissection. The Screw Guides are advanced down to the cortex and locked in position with the Clamp Locking Nuts. The medial hole is drilled first.

A Drill Guide (φ8/φ4) is inserted into the medial Screw Guide, and tapped gently to engage its tip in the cortex. The Drill Bit is introduced down to the bone, and pressed against the cortex to fix the tip before drilling begins. The Graduated Angled Trocar is inserted after this hole is drilled, and final alignment confirmed. The lateral hole is now drilled, the screw length determined, the proximal cortex tapped and the screw inserted. The Graduated Angled Trocar is then removed, and the medial screw inserted using the same technique.

Final Check

A final check is now made to confirm that fracture reduction is satisfactory, and that all four locking screws are correctly inserted through the nail, the screw heads flush with the bone, and the distal ends just protruding beyond the second cortex.

REMOVAL OF THE JIG ASSEMBLY AND CLOSURE

The Proximal Outrigger is removed, the Guide Bar Locking Screw loosened, and the Guide Bar removed. At this stage, the Handle is removed after loosening the Locking Rod a few turns with the SW 5 Wrench. Once the Locking Rod and the Handle have been removed, a Nail End Cap is placed over the end of the nail. The nail end cap is screwed tight with the Hex Screwdriver. Closed suction drainage is advised for the insertion wound. All incisions should be sutured in layers in the usual way. Firm dressings should be applied to prevent hematoma formation. The drainage is removed
after 24-48 hours.

POST-OPERATIVE MANAGEMENT

WEIGHTBEARING

The patient is mobilized on crutches immediately, but the knee is rested in an immobilizer for 1-2 days. Dressings are changed daily, and, after the drain has been removed, the knee may be mobilized freely. With a stable fracture, a patient may weightbear as able, increasing to full weightbearing by 4 weeks. If the fracture is unstable, toe touch weightbearing is permitted immediately, with gradually increasing partial weightbearing over the next 6 weeks. Full weightbearing is only advised once there is some continuity of callus across the fracture site.Fractures with severe comminution, of Winquist-Hansen types IV and V, should be supported before weightbearing with an external brace, if an 8 mm or 9 mm nail has been used, until the fracture is healed.

NAIL REMOVAL

Nail removal may normally be carried out after 18-24 months provided that there is radiological evidence of union. Union may be expected to occur after 6 months with nailing procedures in the tibia. The situation may be different in open fractures, non-unions or corrective osteotomies. In such cases the nail should be left in situ for a minimum of 24 months. The proximal end of the nail is exposed through a small incision. It may be necessary to clear some new bone from the end of the nail. The nail end cap is removed with the Hex Screwdriver, and the **Screw Adapter** is screwed on to the nail, and tightened firmly. This should be accomplished prior to the removal of the proximal locking screws to prevent the nail from deflecting posteriorly.

The locking screws are now all removed. When locking screws require to be removed for any reason, (e.g. nail dynamization or extraction, or in the occasional case where the length of the

chosen locking screw is incorrect), this maybe accomplished using the Locking Screw Extractor as follows: the Extractor is inserted down to the head of the screw, and is turned counterclockwise. The thread on the outside of the locking screw head is a verse thread, so it is necessary to turn the Extractor counterclockwise throughout this procedure. The first turns lock the extractor to the screw head, and further turns will release the screw thread from the bone. Once the thread has been disengaged from the cortex, the screw should be pulled out directly. Further turns at this point will achieve nothing, as no thread remains in the bone. Note that the locking screw is then disengaged from the extractor by turning the latter clockwise, which is the opposite direction to normal. It may be necessary to grip the smooth shaft of the screw with forceps during this procedure.

The nail is then removed, either by manual traction on the Screw Adapter, or by reverse hammering,after screwing the Sliding Hammer on to the proximal end of the adapter.