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Introduction

Preface

The newly developed **CFN - Cannulated Femur Nail** enables the surgical treatment of various fractures of the femur.

Stable, ridged fixation of fractures can be achieved, with the advantage of early weight bearing due to intramedullary insertion.



Screws

32652-XXX Cortical Screw, D=6.5mm

61502-350 Spiral Drill, D=5.0mm, L=350mm, AO Connector

54353-230SH Screwdriver Shank, PRS, Solid, WS 3.5mm,

L=230mm, AO Connector

32475-XX Cortical Screw, D=4.7mm

61427-140 Spiral Drill, Angledrived, D=4.2mm, L=140mm

54353-230SH Screwdriver Shank, PRS, Solid, WS 3.5mm,

L=230mm, AO Connector



Properties

Properties of the material:

- Nail material: TiAl6V4 ELI
- Material of screw: TiAl6V4 ELI
- Easier removal of the implant is necessary
- Improved fatigue strength of the implant
- Reduced risk of inflammation and allergy

Properties of the implant:

- Anatomically shaped
- Single radiolucent insertion guide for left and right sides
- Intramedullary insertion allows early weight bearing
- Multi-direction proximal Locking
- Dynamic interlock options to allow for fracture compression on axial loading without sacrificing rotational stability
- Left and right sided nails

Reamer (optional)

Properties:

- Nitinol shaft with large AO-Connector
- Reamer heads available from 8.0 to 14mm in 0.5 increments
- 5 Reamer blades with 67% free clearance space for low intramedullary pressure and temperature
- Ball tipped guide wire for reaming fits through nail (no change of wire)
- Radiolucent and lightweight tissue protection sleeve with AO Connector and K-wire holes for fixation





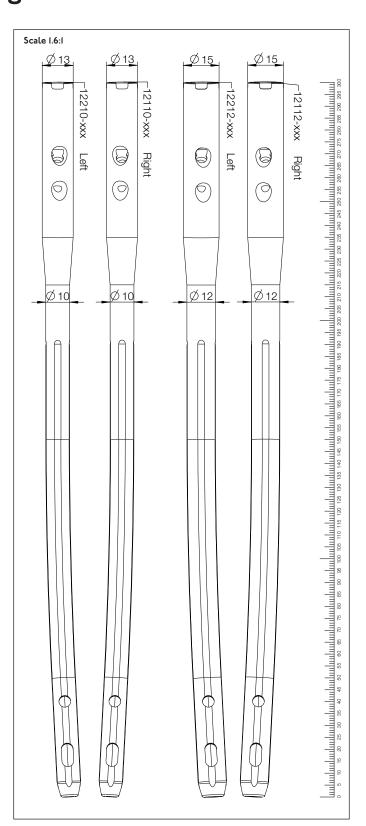
Measurement of nail length

I. Determine the nail length with the template (see right) and a X-Ray

Attention: Scale 1.6:1

- **2.** Determine the nail length with the X-Ray ruler (59203).
- **3.** Insert the calibrated D=2.5mm guide wire with ball tip (35258-800) attach the nail length gauge (59206) and advance it to the cortex. Then read off the required nail length at the end of the gauge.





Indications, Contraindications

Indications:

- Open and closed metaphyseal and diaphyseal fractures
- Subtrochanteric and supracondylar fractures
- Segmental fractures
- Non-unions, mal-unions and delayed union fractures
- Pathological fractures, impending pathological fractures and tumor resections
- Fractures proximal to a total knee arthroplasty

Contraindications:

- Active infection
- Skeletally immature patients
- Severe osteoporosis or inadequate bone stock
- Skin and soft tissue problems
- Foreign body (material) sensitivity
- Obesity
- · Lack of patient compliance

Surgical Technique

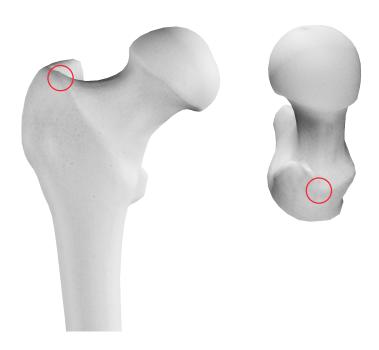


Pre-operative patient planning

- Surgical planning depends on the operative technique individually preferred.
- Recommended position supine on a standard radiolucent operating room table with traction through the injured extremity (AP and lateral fluoroscopic imaging should be confirmed).

Incision

- Incision 2 3cm proximal to the greater trochanter in line with the longitudinal axis of the femur.
- Longitudinally split the fascia and use a trochar or finger palpation to identify the greater trochanter.



Assembly of the insertion guide

hole in the jig. Then push the drill through the drill sleeve in the

appropriate nail interlock hole.



Locating entry portal



- Identification of the insertion portal is extremely important. The drill tip, guide wire or awl should be inserted at the medial edge of the greater trochanter on the AP fluoroscopic view and in line with the longitudinal axis of the femur on the lateral fluoroscopic view.
- Open the proximal medullary canal with the required drill, awl or gimlet to the desired diameter with the appropriate soft tissue protector in place.
- Introduce the D=3.0mm guide wire with ball tip (35301-800) when using the optional available reamer down to the level of the fracture, reduce the fracture and pass the guide wire distally under fluoroscopic guidance. The canal should then be reamed in a sequential manner starting with the smallest reamer and increasing size in 0.5mm increments to I to I.5mm over the desired diameter of the nail.

Optional Reaming



- If appropriate, the canal should be reamed in a sequential manner starting with the smallest reamer and increasing size in 0.5mm increments to 1.0 to 1.5mm over the desired diameter of the nail.
- The usage of the protection sleeve is recommended to avoid injuries of soft tissue.

Note: Reamer heads available from 8.0 to I4mm in 0.5 increments

Note: Ball tipped guide wire will stop the reamer head.

Nailing



- Attach the CFN to the insertion guide and pass the nail over the guide wire as far as possible into the medullary canal by hand.
- When the nail will no longer advance by hand, the impactor screw (II8006-II) or the impaction/retraction rod (II8006-2I) can be gently tapped with the slotted hammer (I-I920) while watching the nail for advancement across the fracture under fluoroscopy.
- If the CFN has been inserted too distally, it can be repositioned manually or back-slapped by using the impaction/retraction rod (II8006-2I) and the slotted hammer (I-I920).

Note: Circumferential indentations (visible under fluoroscopy) in 5mm increments at the distal end of the adapter facilitates the determination of the correct depth.

Attention: Manipulate the nail gently to avoid penetration of the cortex. Please do not hit the insertion guide directly with the hammer (because of material damage)!

Advice: If you lock the nail distally first, it is possible to compress the fracture gap by using the impaction/retraction rod and the slotted hammer to impact the fracture.

Proximal Locking / Femoral neck



- For proximal locking into the femoral neck the screw alignment guide is attached to the handle with the spinning fastener (see page 10).
- Insert the trochar (118007-8) through the D=5.1mm drill sleeve (118007-7) and advance to the cortex through a stab incision.
- Remove the trochar and insert the spiral drill, D=5.0mm, L=350mm, AO Connector (61502-350) to drill through the drill sleeve.
- Measure the screw length (see page 15).



- Insert a D=6.5mm cortical screw (32652-XXX) of appropriate length determined previously through the tissue protection sleeve.
- Verify the correct screw position under fluoroscopy.

Attention: Do not overtighten the screws.

Proximal Locking / Greater to lesser trochanter



- For the proximal Locking into the lesser trochanter the tissue protection sleeve (II8007-5) is inserted directly on the handle (II8007-I)
- Insert the trochar (II8003-I2) through the D=5.Imm drill sleeve (II8007-7) and advance to the cortex through a skin incision.
- Remove the trochar and insert the spiral drill, D=5.0mm, L=350mm, AO Connector (61502-350) to drill through the drill sleeve.
- Measure the screw length (see page 15).



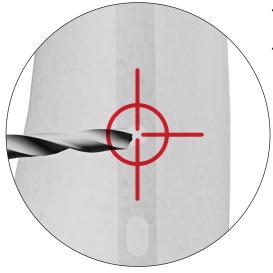
- Insert a D=6.5mm cortical screw (32652-XXX) of appropriate length determined previously through the tissue protection sleeve.
- Verify the correct screw position under fluoroscopy.

Attention: Do not overtighten the screws.

Measuring of proximal screw length

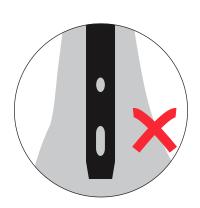


Distal Locking



- Distal locking is carried out using fluoroscopy and perfect circle technique.
- Before locking, the correct reduction should be verified.







- The spiral drill, angledrived, D=4.2mm, L=140mm (61427-140) is used to drill through the medial and lateral cortex. Measure the screw length using the depth gauge (KG.400.06). Insert a D=4.7mm cortical screw (32475-XX) of appropriate length determined previously.
- Additionally, the screw should rise above the lateral cortex at least 2mm
- Verify the correct screw position in the fluoroscopy.

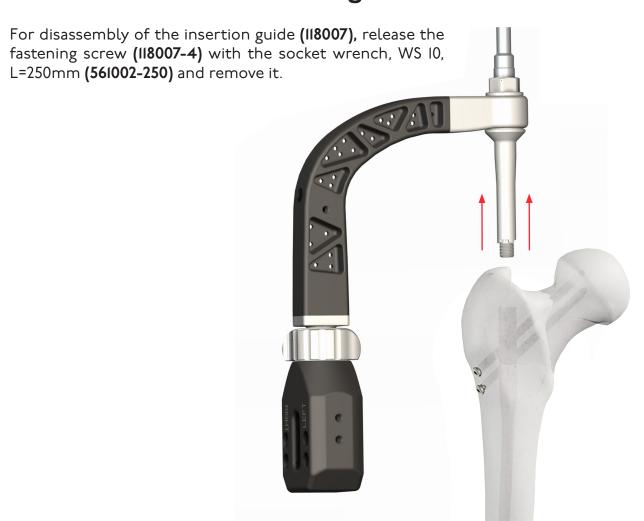
Attention: Do not overtighten the screws.

Secondary dynamization: Insert both medial/lateral screws. If compression is desired, remove the proximal medial/lateral screw.

Measuring of distal screw length

For distal interlocking, the screw length may also be determined using the depth gauge, II0mm, for longer screws (KG.400.06).

Removal of the insertion guide



Endcap insertion

Finally screw the endcap with the screwdriver shank, PRS, solid, WS 3.5mm, L=230mm, AO Connector (54353-230SH) into the proximal end of the nail, which will protect the internal thread of the femur nail against tissue growth, thus facilitating removal of the implant at a later date.

Final verification of nail position under fluoroscopy.



Postoperative treatment

- Standard postoperative protocols for management of femur fractures apply.
- Weight bearing status and range of motion will be determined by the surgeon for the individual needs of the patient.

Nail removal

- Removal is possible, if necessary or desired by the patient. The situation is facilitated by the fact that cold welding never occurs.
- Implant removal is performed after radiographic verification of the healed fracture.
- Skin incision over the previous surgical site.
- Remove the endcap and all screws with the screwdriver shank, PRS, solid, WS 3.5mm, L=230mm, AO Connector (54353-230SH).
- Finally, the extraction rod (II8007-9) is screwed into the nail using the flatwrench, WS I7 (70017).
- Using light taps with the slotted hammer (1-1920) to remove the nail from the medullary space.
- The problem of cold welding was resolved by using a special surface treatment (for further information see page 22).



Information



Dotize®

Chemical process - anodization in a strong alkaline solution*

Type III anodization

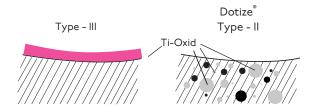
- Layer thickness 60-200nm
 - + Different colors

Discoloration

 Implant surface remains sensitive to: Chipping Peeling

Dotize Type II anodization

- Layer thickness 2000-I0 000nm
 - + Film becomes an interstitial part of the titanium
 - No visible cosmetic effect



Anodization Type II leads to following benefits*

- Oxygen and silicon absorbing conversion layer
- Decrease in protein adsorption
- Closing of micro pores and micro cracks
- Reduced risk of inflammation and allergy
- Hardened titanium surface
- Reduced tendency of cold welding of titanium implants
- Increased fatigue resistance of implants
- Improved wear and friction characteristics

Order list

Cannulated Femur Nail, D=10mm, L=300mm, Right Cannulated Femur Nail, D=10mm, L=320mm, Right	12110-300 12110-320
Cannulated Femur Nail, D=10mm, L=340mm, Right	12110-340
Cannulated Femur Nail, D=10mm, L=360mm, Right	12110-360
Cannulated Femur Nail, D=10mm, L=380mm, Right	12110-380
Cannulated Femur Nail, D=10mm, L=400mm, Right	12110-400
Cannulated Femur Nail, D=10mm, L=420mm, Right	12110-420
Cannulated Femur Nail, D=10mm, L=440mm, Right	12110-440
Cannulated Femur Nail, D=10mm, L=460mm, Right	12110-460
Cannulated Femur Nail, D=10mm, L=480mm, Right	12110-480
Cannulated Femur Nail, D=10mm, L=300mm, Left	12210-300
Cannulated Femur Nail, D=10mm, L=320mm, Left	12210-320
Cannulated Femur Nail, D=10mm, L=340mm, Left	12210-340
Cannulated Femur Nail, D=10mm, L=360mm, Left	12210-360
Cannulated Femur Nail, D=10mm, L=380mm, Left	12210-380
Cannulated Femur Nail, D=10mm, L=400mm, Left	12210-400
Cannulated Femur Nail, D=10mm, L=420mm, Left	12210-420
Cannulated Femur Nail, D=10mm, L=440mm, Left	12210-440
Cannulated Femur Nail, D=10mm, L=460mm, Left	12210-460
Cannulated Femur Nail, D=10mm, L=480mm, Left	12210-480
Cannulated Femur Nail, D=12mm, L=300mm, Right	12112-300
Cannulated Femur Nail, D=12mm, L=320mm, Right	12112-315
Cannulated Femur Nail, D=12mm, L=320mm, Right Cannulated Femur Nail, D=12mm, L=340mm, Right	12112-315 12112-340
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Order list

Cortical Screw, D=4.7mm, L=28mm	32475-28	
Cortical Screw, D=4.7mm, L=30mm	32475-30	- Samanananananananananananananananananana
Cortical Screw, D=4.7mm, L=32mm	32475-32	
Cortical Screw, D=4.7mm, L=34mm	32475-34	
Cortical Screw, D=4.7mm, L=36mm	32475-36	
Cortical Screw, D=4.7mm, L=38mm	32475-38	
Cortical Screw, D=4.7mm, L=40mm	32475-40	
Cortical Screw, D=4.7mm, L=42mm	32475-42	
Cortical Screw, D=4.7mm, L=44mm	32475-44	
Cortical Screw, D=4.7mm, L=48mm	32475-48	
Cortical Screw, D=4.7mm, L=52mm	32475-52	
Cortical Screw, D=4.7mm, L=56mm	32475-56	
Cortical Screw, D=4.7mm, L=60mm	32475-60	
Cortical Screw, D=4.7mm, L=65mm	32475-65	
Cortical Screw, D=4.7mm, L=70mm	32475-70	
Cortical Screw, D=4.7mm, L=75mm	32475-75	
Cortical Screw, D=4.7mm, L=80mm	32475-80	
Cortical Screw, D=6.5mm, L=40mm	32652-40	
Cortical Screw, D=6.5mm, L=44mm	32652-44	Manufacture Commencer
Cortical Screw, D=6.5mm, L=48mm	32652-48	
Cortical Screw, D=6.5mm, L=52mm	32652-52	
Cortical Screw, D=6.5mm, L=56mm	32652-56	
Cortical Screw, D=0.5mm, L=60mm	32652-60	
	32652-64	
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Cortical Screw, D=6.5mm, L=68mm	32652-68	
Cortical Screw, D=6.5mm, L=72mm	32652-72	
Cortical Screw, D=6.5mm, L=76mm	32652-76	
Cortical Screw, D=6.5mm, L=80mm	32652-80	
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Cortical Screw, D=6.5mm, L=88mm	32652-88	
Cortical Screw, D=6.5mm, L=92mm	32652-92	
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Cortical Screw, D=6.5mm, L=100mm	32652-100	
Cortical Screw, D=6.5mm, L=105mm	32652-105	
Cortical Screw, D=6.5mm, L=110mm	32652-110	
Cortical Screw, D=6.5mm, L=115mm	32652-115	
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Handle, 25mm, AO Connector	53011	
Screwdriver Shank, PRS, Solid, WS 3.5mm, L=230mm, AO Connector	54353-230SH	
D 11 C 110 C 1	KC 100.07	
Depth Gauge, 110mm, for longer screws	KG.400.06	
X-Ray Ruler, Cannulated Femur Nail	59203	
Depth Gauge, for Cannulated Tibia & Femur Nail	59204 ———	
Nail Length Gauge	59206	10 (1700 — 2) 10 (1700 — 2)
Spiral Drill, Angledrived, D=4.2mm, L=140mm	61427-140	· ·
Spiral Drill, D=5.0mm, L=350mm, AO Connector	61502-350	
	01302-330	
Guide Wire, Steel, D=2.5mm, L=800mm	35252-800	
Guide Wire, Steel, with ball tip, D=2.5mm, L=800mm	35258-800	c
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-,, · · · · · · · · · · · ·		

Impactor Screw, CNS	118006-11	
Socket Wrench, WS 10, L=250mm	561002-250	
Extraction Rod, Cannulated Femur Nail	118007-9	
Impaction/Retraction Rod, CNS		÷
Slotted Hammer	1-1920	
Endcap, Standard, Cannulated Femur Nail	118007-11	
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Endcap, +10mm, Cannulated Femur Nail	118007-13	
Endcap, +15mm, Cannulated Femur Nail	118007-14	
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Flat Wrench, WS 10	70010	5
Flat Wrench, WS 17	70017	
Flat Wrench, WS 20	70020	
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Perthes Awl, 16cm	9-1452	O
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Sterilization Tray, Cannulated Femur Nail	50245	
Insertion Guide, Cannulated Femur Nail	118007	

Order list

Spare Parts List Insertion Guide / Optional (on request)		
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Jig, Cannulated Femur Nail	118007-2	
Fastening Nut, CNS	118006-4	jn .
Adapter, Cannulated Femur Nail	118007-3	
Fastening Screw, Cannulated Femur Nail	118007-4	¢=====
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Trochar, Cannulated Femur Nail	118007-8	
Clamping Screw	118003-12	**************************************
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Nitinol Reamer Shaft, D=5.0mm, L=473mm, AO Connector	63500-473	**************************************
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Outer Protection Sleeve, D=17.0mm, Radiolucent, Suprapatellar Trochar, Cannulated, Suprapatellar Protection Sleeve, D=15.0mm, AO Connector		

For detailed cleaning and sterilization instructions, please refer to package insert.



Tray setting



Notes



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