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Anatomic Distal Femoral Locking Nail

Edition 201911

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Warning

This publication describes the recommended procedures for using Double Engine devices and instruments. It offers guidance that you should pay attention to. But as with any such technical guide, the guide alone does not provide sufficient background for direct use of the instrument set, each surgeon should also consider the particular needs of each patient and make appropriate adjustments when required. Instruction by experienced surgeon is still highly recommended.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instruments must be disassembled for cleaning. Please follow the instructions provided in our *Reprocessing, Care and Maintenance Guide* (*RCMG*-2012).

Please refer to *Package Insert* for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Caution

The implants are designed for temporary fixation of fractured bone fragments until the bone heals. Therefore, if bone does not heal or bone consolidation is delayed or not sufficient, the system may break. Post-operative care under the guidance of the surgeon is also very important and it must be to ensure the promotion of bone consolidation.





Surgical Technique

Indications

- Open and closed femoral fractures;
- Pseudoarthrosis and correction osteotomy;
- Pathologic fractures, impending pathologic fractures, and tumor resections;
- Supracondylar fractures, including those with intra-articular extension;
- Fractures distal to a total hip prosthesis;
- Nonunions and malunions.

Patient Position

Estimate diameter and length using the radiographic ruler for the Distal Femoral Nail II. To estimate the nail diameter, place the radiographic ruler on the lateral x-ray of the uninjured femur and measure the diameter of the medullary canal at the narrowest part that will contain the nail. To estimate the nail length, place the radiographic ruler on the AP x-ray of the uninjured femur and select the appropriate nail length based on patient anatomy.

Notes

When choosing the nail size, consider canal diameter, fracture pattern, patient anatomy and post-operative protocol

Patient Position

Position the patient supine on the operating table. The knee of the injured leg should be flexed 70°-90°. A leg roll may be used or the lower leg be flexed by lowering part of the table to allow proper reduction and stabilization of the reduced fracture. Position the image intensifier in such a way that visualization of the entire femur is possible in anterior-posterior (AP) as well as lateral views.





STEP 1

OPEN FEMUR 1.2 Determine entry point 1.1 Approach The entry point for the nail is in the axis of the medullary canal and in the intercondylar notch, just anterior and lateral to the femoral Make a medial parapatellar approach. attachment of the posterior cruciate ligament.



1.3 Insert guide wire

111340600	Protection sleeve
111340500	Drill Sleeve, for guide wire
111220200	Guide Wire, with threaded tip

Insert the protection sleeve and the drill sleeve for guide wire through the incision to the bone. Insert the guide wire with threaded tip to a depth of 10 to 15cm, taking into consideration the 7° to 9° valgus angle of the anatomic axis of the femur. AP and lateral image intensifier control is mandatory.



1.4 Open medullary canal

11340600	Protection sleeve
11220200	Guide Wire, with threaded tip
11340400	Reaming Drill, proximal

Remove the drill sleeve. Guide the reaming drill through the protection sleeve and over the guide wire to the bone. Drill to a depth of approximately 3cm. Remove the protection sleeve and the guide wire. Do not re-use the guide wire. Remove the bone and cartilage debris and thoroughly rinse the knee joint.

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Alternative

111340800 Awl, cannulated 110350700 Tissue Protector

The medullary canal can also be opened with the cannulated awl.

111190900 Reduction Rod 111191000 Guide Wire, with olive head

If needed, insert the reduction rod into the medullary canal, and guide the guide wire with olive head over reduction rod into the distal medullary canal to perform reduction.



STEP 2

CALIBRATE NAIL

Select a nail with appropriate length and diameter. Connect the nail to the insertion handle. Wholly assembled to calibrate the nail. Note: The nail needs to be calibrated preoperatively.



1.5 Determine the nail length

111340100 Radiographic Ruler

Position the radiographic ruler on the thigh parallel to the femur. Read nail length directly from the ruler under the image intensifier. Locate the round diameter gauge over the femoral isthmus at the narrowest part that will contain the nail. Select the nail diameter with which the medullary canal-to-cortex transition is still visible on both sides of the ruler in the AP view.

Note: Compare the nail length and diameter with the preoperative estimate results.

1.6 Ream the medullary canal

Starting with the smallest diameter reaming head, ream a diameter of 0.5 mm increments and advance the reamer with steady, moderate pressure. Partially retract the reamer repeatedly to clear debris from the medullary canal. The maximum reaming diameter is 13.5mm. The diameter of selected nail should be 0.5 mm smaller than the diameter of medullary canal. Avoid pulling out the guide wire when removing flexible reamer.



3.2 Insert nail

111191000 Guide Wire, with olive head 111342400 Insertion Handle 111342600 Connecting Screw, for Insertion Handle

Remove reduction rod, leaving the guide wire with olive head in the medullary canal. Orient the insertion handle anteriorly to insert the nail over the guide wire with olive head into the medullary canal. Insert the nail by hand as far as possible twisting gently. Note: The nail rotates approximately 90° during insertion. The insertion handle rotates from anterior to lateral during insertion of the last one-third of the nail length.

Anatomic Distal Femoral Locking Nail



STEP 3

INSERT NAIL

3.1 Assemble insertion instruments

111342400	Insertion Handle
111342600	Connecting Screw, for Insertion Handle
111192600	Wrench, for Connecting Screw

111197200 Universal Wrench, SW6.5

With the insertion handle facing laterally, match the teeth on the handle with the notches in the nail. The anterior curvature of the implant must be aligned with that of the femur. Slide the connecting screw through the insertion handle and screw it into the nail. Tighten the connecting screw with the wrench without stripping it.

Optional instrument

11192700	Connector Block
11192800	Connector Shaft
11193200	Slide Hammer
10351200	Ratchet Wrench, SW1

If hammering with the slide hammer is necessary for insertion, attach the connector block and connector shaft to the insertion handle and tighten the assembly. Use slide hammer blows to insert the nail.

Note: After nail insertion, check that the connecting screw is still tight as it could have loosened during hammering. Do not attach the aiming arm for standard locking or spiral blade locking, respectively, to the insertion handle until the nail is fully inserted. Otherwise, the aiming arm may loosen during nail insertion.







STEP 4 **PROXIMAL LOCKING**

Option A Standard Locking

The standard locking is performed with two 6.0 mm locking screws.

A1 Assemble the three-part trocar combinations

111343400	Protection Sleeve, long, φ10/φ8.1
111343500	Drill Sleeve, $\phi 8.1/\phi 4.8$
111343600	Trocar, φ4.8
111347800	Guide Block for Protection Sleeve

Assemble the guide block onto the insertion handle, and then insert the three-part trocar combinations through the caudal hole of guide block, make a stab incision and remove the trocar.

A2 Insert the first locking screw

111343700	Drill Bit, q4.8, length 300mm
111343700	Drill Bit, φ4.8, length 350mm
111344000	Depth Gauge
111344100	Screwdriver, Stardrive, T25

Drill through both cortices using the drill bit, stopping just after penetrating the far cortex. Confirm the drill bit position radiographically. Make sure the drill sleeve is in contact with the bone. Remove the drill sleeve and insert the depth gauge through the protection sleeve to determine the length of locking screw by adding 2mm to the reading. Insert the locking screw through the protection sleeve and make sure the screw head is in contact with the medial cortex.





Repeat steps A2 for inserting the second locking screw in the cranial screw hole on the guide block.

Option B Spiral Blade Locking

The spiral blade locking option with one spiral blade and one 6.0 mm locking screw is used for patients with an osteoporotic bone structure and/or extensive and complex supra-condylar comminuted fracture areas.

B1 Assemble the three-part trocar combinations

111342500	Guide Block for Spiral Blade
111344400	Protection Sleeve @15.5/@12.7
111344500	Drill Sleeve for Guide Wire $0127/032$
111344600	Trocar. φ3.2

Assemble the guide block for spiral blade onto the insertion handle, and then insert the three-part trocar combinations (protection sleeve, drill sleeve and trocar) through the caudal hole on the guide block. Make a stab incision and advance the combination to the lateral cortex.



B2 Insert guide wire and measure the length for spiral blade

111220200	Guide Wire With Threaded Tip
111344800	Direct Measuring Device for Guide Wire

Insert the Countersink over the guide wire through the protection Insert the guide wire into the condyles until its tip is flush with the sleeve and open the lateral cortex manually or with a power tool. The medial cortex. Confirm guide wire position radiographically. Make drill bit should open the lateral cortex only to prepare the seat of the sure the drill sleeve is in contact with the bone and read the length spiral blade head. The automatic stop prevents the drill bit from for direct measuring device for guide wire. Remove the drill sleeve. penetrating too far. Remove the drill bit and protection sleeve.



B4 Insert spiral blade

111344900	Impactorfor Spiral Blad
111345000	Connecting Shaft
111193200	Slide Hammer

Attach the spiral blade of the previously determined length firmly to the impactor for spiral blade. Bring the spiral blade and the impactor over the guide wire to the bone. Insert the blade manually or by gentle hammer taps to the connecting shaft attached to the impactor. The correct insertion depth is reached when the blade head is flush with the lateral cortex. Verify under image intensification. Detach the insertion instruments from the blade and remove the guide wire.



B3 Open cortex

111344700 Countersink



B5 Insert 6.0mm Locking Screw

Repeat steps A1and A2 to insert a locking screw





STEP 5

DISTAL LOCKING

Distal locking for nails is done using three 4.9 mm locking screws: a static hole in AP direction, a static hole and a dynamic locking slot in lateral direction. These locking options make immediate or secondary dynamization of the fracture possible.

5.1 Assemble the Calibrating Pin

- 111193900 Locking Screw for Aiming Shaft, M6
- 111346500 Aiming Arm, distal
- 110355500 Protection Sleeve, φ10/φ8.1
- 110355600 Drill Sleeve, φ8.1/φ5
- 110355700 Trocar, φ8.1

110355400 Drill Bit, φ5.0, length 250mm 110355300 Drill Bit with flat head 111347100 Calibrating Pin 111347200 U-Clip

Select and connect the proximal and distal aiming shaft to insertion handle according to the length of selected nail, adjust the Locking Screw for Aming Shaft based on the operation side. Connect distal aiming arm to the distal aiming shaft. Insert protection sleeve, drill sleeve and trocar through the location hole in the distal aiming arm, make a stab incision and insert the trocar to the bone.



Remove the trocar and insert the drill sleeve to the bone. Advance the drill bit over the drill sleeve through cortical bone. Clean the bone debris in the platform using the drill bit with flat head. Extract the drill bit, drill sleeve and place the calibrating pin. Ensure the calibrating pin is in contact with the nail platform and use the U-clip to connect the calibrating pin and aiming shaft tightly.

5.2 Drill

111355500 Protection Sleeve,φ10/φ8.1 111343400 Protection Sleeve, long, φ10/φ8.1 111345900 Drill Sleeve. ø8.1/ø4.2 111346000 Trocar, φ4.2 110310700 Drill Bit, φ4.2, 300mm 110314700 Drill Bit, φ4.2, 350mm

It is recommended to start with the drill of the distal dynamic locking hole. Insert both three-part trocar combinations (protection sleeve, drill sleeve and trocar) through two holes in lateral direction in the distal aiming shaft, make a stab incision and insert the trocar to the bone.



Remove the distal trocar, insert the short 4.2 mm drill bit and drill through both cortices until the tip of the drill bit penetrates the medial far cortex. Remove the proximal trocar, drill the long 4.2 mm drill bit through both cortices.

Tip: For greater drill bit control, discontinue drill power after perforating the near cortex.



5.4 Insert locking screw for dynamization

Remove the short drill bit and sleeve, and repeat the steps 5.3 to insert the distal locking screw for dynamization.

5.3 Insert first distal locking screw

111344000 Depth Gauge 111344100 Screwdriver, Stardrive, T25

Remove the long drill bit and drill sleeve with reserving the short drill bit. Read off the locking screw length using the depth gauge. Ensure that the protection sleeve is in contact with the bone and the hook grasps the far cortex. It is recommended that you start with the insertion of the proximal locking screw. Remove depth gauge. Insert the locking screw with previously measured length using the T25 stardrive screwdriver. When the protection sleeve meets the "0" scale on the screwdriver, the locking screw is fully inserted.

5.5 Insert the screw in AP direction

Insert the three-part trocar combinations through hole in the distal aiming arm, make a stab incision and insert the trocar to the bone. Remove the trocar, insert 4.2mm drill bit and drill through both cortices until the tip of the drill bit penetrates the medial far cortex. Remove the drill bit and drill sleeve. Read off the locking screw length using the depth gauge. Remove depth gauge. Insert the locking screw with previously measured length using the T25 stardrive screwdriver.





STEP 6 **INSERT END CAP**

111226400 Screwdriver Shaft for End Cap 111190600 T-Handle with Quick Coupling

The use of the end cap is mandatory to prevent bone in growth into the nail and lock the spiral blade proximally providing a stable angle. Remove the insertion handle, aiming shaft and connecting screw. Using the screwdriver, align the end cap with the nail axis and fix it. To minimize the chance of cross-threading, turn the end cap counterclockwise until the thread of the end cap aligns with that of the nail. By turning clockwise, completely screw the end cap into the nail, so that the spiral blade is fixed. Tighten the end cap firmly.



STEP 7

REMOVE IMPLANT Implant removal is an optional procedure.

7.1 Remove end cap

111226400 Screwdriver Shaft for End Cap 111190600 T-Handle with Quick Coupling

Remove the ingrown tissue from the stardrive recess of the end cap and the locking implants. Unscrew the end cap using the screwdriver shaft for end cap.





7.2 Remove the locking implants

- 111344100 Screwdriver, Stardrive, T25
- 111347300 Extraction Screw for Spiral Blade
- 111193200 Slide Hammer
- 110354300 Extraction Screw for Distal Femoral Nail

Spiral blade: screw the extraction screw for spiral blade into the blade head and screw the Extraction Screw for Distal Femoral Nail onto the extraction screw. Knock the spiral blade out with the slide hammer.

Locking screw 6.0mm: unscrew the 6.0mm locking screw using stardrive screwdriver T25.

Locking Screw 4.9mm: unscrew the 4.9mm locking screw using stardrive screwdriver T25.

Note: Remove the locking screws with T25 screwdriver until there is only one locking screw left.



7.3 Remove the nail

10354300	Extraction Screw for Distal Femoral Nail
10351200	Ratchet Wrench, SW11
11344100	Screwdriver, Stardrive, T25
11193200	Slide Hammer

Before removing the last locking implant, screw the extraction screw for DFN into the nail and tighten with the ratchet wrench. The last locking implant prevents the nail from rotating or sliding away. The last locking implant using the stardrive screwdriver T25. Attach the slide hammer to the extraction screw and knock the nail out with gentle blows.







Instruments 111420000 T-Handle with Quick Coupling 111340100 Radiographic Ruler 111190600 Guide Wire, with threaded tip, 111220200 φ3.2, length 320mm Awl, cannulated 111340800 111197300 Holder for Guide Wire 110350700 **Tissue Protector** Reaming Drill, proximal 111340400 Reduction Rod 111190900 Drill Sleeve, for Guide Wire 111340500 Guide Wire, with olive head, 111191000 φ2.5, length 1000mm Insertion Handle 111342400 111340600 **Protection Sleeve**







111342500	Guide Block for Spiral Blade	110311000	Wrench for Fixation Sleeve, SW3
111342600	Connecting Screw, for Insertion Handle	111193200	Slide Hammer
111192600	Wrench, for Connecting Screw	111343400	Protection Sleeve, long, φ10/φ8.1
111192700	Connector Block	111343500	Drill Sleeve, φ8.1/φ4.8
		111343600	Trocar, φ4.8
111192800	Connector Shaft	111343700	Drill Bit, φ4.8, length 300mm
110351200	Ratchet Wrench, SW11	111343800	Drill Bit, φ4.8, length 350mm
110354300	Extraction Screw for Distal Femoral Nail	 111343900	Fixation Sleeve, φ4.8











111344000	Depth Gauge		111344900	Impactor for Spiral Blade
111344100	Screwdriver, Stardrive, T25		111345000	Connecting Shaft
111344300	Screwdriver Shaft, Stardrive, T25		111345100	Proximal Aiming Shaft, 160-200
111344400	Protection Sleeve, φ15.5/φ12.7		111345200	Distal Aiming Shaft, 160-200
111344500	Drill Sleeve, for Guide Wire, φ12.7/φ3.2		111345300	Proximal Aiming Shaft, 220-260
111344600	Trocar, φ3.2		111345400	Distal Aiming Shaft, 220-260
111344700	Countersink		111345500	Proximal Aiming Shaft, 280-400
111344800	Direct Measuring Device for Guide Wire	(19) 年 年 月 年 日 21 年 田 多 め 方 め	111345600	Distal Aiming Shaft, 280-400





111345700	Locking Screw for Insertion Hand		111346500	Aiming Arm, distal
110355800	L-Wrench, hexagonal		110355700	Trocar, φ8.1
		11	110355500	Protection Sleeve, φ10/φ8.1
111345900	Drill Sleeve, $\phi 8.1/\phi 4.2$			
		\sim	110355600	Drill Sleeve, q8.1/q5
111346000	Trocar, φ4.2			
110310700	Drill Bit, φ4.2, length 300mm	41 <i>69/21</i> 64	110355400	Drill Bit, φ5.0, length 250mm
			110355300	Drill Bit with flat head
110314700	Drill Bit, φ4.2, length 350mm	410416	110355500	
110310900	Fixation Sleeve, φ4.2		111347100	Calibrating Pin
111193900	Locking Screw for Aiming Shaft,			
	M6		111347200	U-Clip















