DFN Distal Femoral Nail



This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.



Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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MRI Information

The Distal Femoral Nail DFN is indicated for the stabilization of fractures of the distal femur. It can also be used for diaphyseal fractures in which a retrograde approach is indicated (e.g. ipsilateral tibia and/or patella fractures, proximal or distal endoprosthesis, adipositas permagna). These include according to the AO classification:

Indications

- Fractures of type 33-A1 to A3
- Fractures of type 33-C1 to C3.1
- Fractures of type 32-A to C



Contraindications

- Fractures of type 33-B, 33-C3.2 and 33-C3.3
- Proximal femoral fractures and high subtrochanteric fractures

Implants



Available non-sterile or sterile packed. Add "S" to the catalogue number to order sterile products Careful preoperative planning with clear classification of the fracture and correct choice of implants are mandatory for a successful surgical result.

1 Position patient

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 visualisation of the entire femur is possible in anterior-posterior (AP) as well as lateral views.

2 Reduce fracture

 If possible, carry out closed reduction under image intensifier control. In some cases the use of the Large Distractor (394.350) is required.

Note: After repositioning, and prior to the insertion of the nail, intra-articular fractures should be definitely stabilized with two interfragmentary lag screws. Position the screws so as not to interfere with the path of the nail. The intramed-ullary canal and the nail are slightly dorsal, therefore, lag screws are placed ventrally.

3 Determine nail length

Position the image intensifier for an AP view of the distal femur (Position 1). With long forceps, hold the Radiographic Ruler (357.122) parallel to and on the same level as the femur. Adjust the ruler until the distal end is at the desired nail insertion depth. Mark the skin laterally.

Move the image intensifier to the proximal femur (Position 2), place the distal end of the ruler on the skin mark, and take an AP image of the middle third of the femur (for short nails) and of the proximal femur (for long nails). Verify fracture reduction and read the nail length from the ruler image. When using a long nail, select its length so that it can be locked level with the lesser Trochanter.



4 Determine nail diameter

Place the radiographic ruler perpendicular to the femur and position it over the isthmus to confirm the nail diameter. Choose the nail diameter with which the transition between the medullary canal and the cortex is still visible left and right of the marking.



5 Incision

For 33-A.X and 32-X.X fractures, either make a transligamentar (ligamentum patellae) or a medial parapatellar incision. For 33-C.X fractures always make a medial parapatellar approach.



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The Distal Femoral Nail may be used for either reamed or unreamed application.

Determine nail entry point and insert guide wire 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 attachment of the posterior cruciate ligament.

Insert the Protection Sleeve 17.0/15.0 (357.530) and the Drill Sleeve (357.531) through the incision to the bone. Insert the calibrated Guide Wire \emptyset 3.2 mm (357.129) to a depth of 10 to 15 cm, taking into consideration the 7° to 9° valgus angle of the anatomic axis of the femur. AP and

Iateral image intensifier control is mandatory.



7 Open medullary canal

Place the cannulated Drill Bit Ø 13.0 mm (351.270) into a cannulated power drill. Guide the drill bit through the protection sleeve and over the guide wire to the bone. Drill to a depth of approximately 30 mm. Remove the protection sleeve, the drill sleeve and the guide wire. Do not re-use the guide wire.

Remove the bone and cartilage debris and thoroughly rinse the knee joint.

Alternative

The medullary canal can also be opened with the Large Reverse Awl (351.110).

Reaming of the femur may be indicated depending on the fracture type or if the medullary canal is too narrow. If reaming is not indicated proceed with step 9.



8 Ream medullary cavity with SynReam (Option)

1 Assemble reduction system

Assemble the reduction system of the SynReam Intramedullary Reaming System (189.060): Attach the T-Handle (351.150) at the rear of the SynReam Flexible Shaft (352.040) and a Reduction Head (352.050 or 352.055) at the front.



2 Reduce fracture

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To secure the reduction head, insert the SynReam Reaming Rod \oslash 2.5 mm (352.032, length 950 mm or 352.033, length 1150 mm) in a retrograde direction up to the olive. The olive must be located in the reduction head throughout reduction. Insert the assembled reduction system with the SynReam reaming rod into the medullary cavity and reduce the distal fragments under image intensifier control.

Note: Always reduce with the reaming rod, since secure fixation can only be ensured if the reduction system is used in conjunction with the reaming rod. Using the reduction system without the reaming rod entails the risk of losing the reduction head in the medullary canal.



3 Remove reduction instruments

After completing the reduction, remove the reduction instruments with the exception of the reaming rod, which must remain in the medullary cavity.



4 Assemble the reaming system

Connect the SynReam Flexible Shaft (352.040) to the drill and plug the first SynReam Medullary Reamer Head (352.085) onto the shaft. The reamer heads can be picked up directly, without hand contact, from the insert for medullary reamer heads using the SynReam flexible shaft.

Start with the smallest reamer head (\emptyset 8.5 mm, 352.085) and then increase in 0.5 mm increments using the larger reamer heads (352.090–190). The reaming depth should be identical to the chosen nail length.



5 Insert reaming system

Insert the assembled reaming system, without rotating it, over the SynReam reaming rod into the medullary canal. Use the Tissue Protector (351.050) to spare the soft tissues.



6 Ream medullary canal

Ream the medullary canal according to the standard procedure. Advance the reamer slowly and steadily at maximum drill speed. Secure the SynReam reaming rod with the Holding Forceps for SynReam Reaming Rod (351.782) to prevent it from rotating during reaming.

Note: Do not force the reamer.

Note: Only ream over the SynReam Reaming Rod \emptyset 2.5 mm (352.032, length 950 mm or 352.033, length 1150 mm), since the rod ensures that a secure connection is maintained between the reamer and the flexible shaft.



7 Change reamer head

Having reamed the medullary cavity along its full length, retract the SynReam flexible shaft with the first reamer head until the whole reamer head is visible. Grasp the reaming rod with the Holding Forceps for SynReam Reaming Rod (351.782) immediately above the bone insertion point and hold in situ to avoid loss of reduction. Draw the SynReam flexible shaft through the slot of the Insert with Removing Device for SynReam Medullary Reamers (689.063) so as to remove the used reamer head without touching it.

The reamer head of the next size up can be picked up directly, without hand contact, from the insert for medullary reamer heads using the SynReam flexible shaft.



8 Complete medullary reaming

Repeat steps 5 to 7 for each additional Reamer Head (352.090–190) until the medullary canal is reamed to the desired diameter. Reaming is usually performed with increments of 0.5 mm.

Note: Only ream over the SynReam Reaming Rod \emptyset 2.5 mm (352.032 or 352.033), since the rod ensures that a secure connection is maintained between the reamer head and the flexible shaft.

Loosen blocked medullary reamer heads with left-right turns or with gentle hammer taps to the Holding Forceps for SynReam Reaming Rod (351.782) fastened to the SynReam Reaming Rod \varnothing 2.5 mm (352.032 or 352.033).



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9 Attach nail to insertion handle

With the Insertion Handle (357.112) 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. Note the inscription ANTERIOR on the nail.

Slide the Connecting Screw (357.135) through the insertion handle and screw it into the nail. Tighten the connecting screw with the Pin Wrench (321.170) without stripping it.



10 Insert nail

If hammering with the Slotted Hammer (357.026) is necessary for insertion, attach the Hammer Guide (357.117) to the connecting screw and tighten the assembly.

Insert the nail by hand as far as possible twisting gently. When using a guide rod, slide the Cannulated Nail Ø 12.0 mm over the guide rod into the femoral canal.
Monitor nail passage through the fracture under image intensification.

If necessary, insert the nail using light hammer blows with either the slotted hammer and hammer guide or with a Hammer (399.430/399.505). Using the distal end of the connecting screw as striking surface advance the nail until its distal end is 2 to 5 mm beyond the articular cartilage. The insertion depth is indicated by the grooves on the shaft of the insertion handle. Remove the guide rod.



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.

The standard locking is performed with two Locking Screws \varnothing 6.0 mm (450.862–872).

Spiral blade locking see page 16 (steps 11 to 17).



11 Mount aiming arm and insert trocar assembly

Attach the Aiming Arm for Standard Locking (357.115) to the insertion handle. Insert the turquoise triple trocar assembly (Protection Sleeve 11.0/8.0 (357.118), Drill Sleeve 8.0/4.9 (357.097) and Trocar \emptyset 4.9 mm (357.098)) through the cranial hole of the aiming arm and, after a stab incision, to the bone. Remove the trocar.



12 Drill and measure length for locking screw

Drill through both cortices using the calibrated Drill Bit Ø 4.9 mm (357.099) stopping just after penetrating the far cortex. Confirm the drill bit position radiographically. Make sure the drill sleeve is in contact with the bone and read the length for the locking screw from the ringmarks on the drill bit. The locking screw should not surpass the medial cortex by more than 2 mm.

Note: Since drill bit position directly represents locking screw position in bone, the locking screw will be too long if the drill bit is over inserted, or if the drill sleeve is not pressed down to the cortex.



Alternative

The Depth Gauge for Locking Bolts (357.791) may be used to determine the length of the locking screw. Remove the Drill Sleeve 8.0/4.9 and insert the measuring hook through the Protection Sleeve 11.0/8.0. Determine the length of the locking screw by adding 2 mm to the reading on the depth gauge.



13 Insert first locking screw

Insert the locking screw through the Protection Sleeve 11.0/8.0 using the Hexagonal Screwdriver (314.750) and make sure the screw head is in contact with the medial cortex. The locking screw should surpass the medial cortex by at least 2 mm, but not more than 4 mm.



14 Insert second locking screw

Repeat steps 11 to 13 for inserting the second locking
 screw in the caudal screw hole on the aiming arm.

Note: For standard locking use two locking screws whenever possible.

15 Proximal locking

Proximal locking for nails of 160 - 240 mm in length is done using two Locking Bolts \varnothing 4.9 mm which are inserted laterally. Nails of 300 mm or more are provided with a static hole in lateral direction, and a static hole and a dynamic locking slot in AP direction. These locking options make immediate or secondary dynamization of the fracture possible. The AP approach facilitates locking at the lesser trochanter level.

Align image

Check fracture reduction, the correct alignment of the fragments, and the correct length of the femur.

Align the image intensifier so that the distal hole is visible as a perfect circle in the centre of the image.



Round (correct)



Oval (incorrect)



Determine incision point



Centre drill bit



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16 Make incision

Oetermine the incision point and make a stab incision.

17 Drill

Under image intensification, insert the tip of the Drill Bit Ø 4.0 mm for the radiolucent drive through the incision and place it on the bone.

Tilt the drive until the drill bit appears centred in the locking hole. The drill bit will nearly fill out the locking hole image. Holding the drill in this position, drill through both cortices until the tip of the drill bit just penetrates the medial cortex.

Alternative

If there is no radiolucent drive available and locking is performed with the standard freehand technique use the three-flute Drill Bit \varnothing 4.0 mm (315.400).

18 Measure length for locking bolt and insert locking bolt

- Measure the length for the locking bolt with the Depth Gauge for Locking Bolts (357.791). The length of the locking bolt is determined by adding at least 2, but not more than 4 mm to the length read from the depth gauge.
- Insert the locking bolt using the hexagonal screwdriver.



19 Insert end cap

The use of the turquoise End Cap for Locking Screw (451.896) is mandatory. It fulfills two functions: It prevents bone ingrowth into the nail and blocks the distal Locking Screw \emptyset 6.0 mm thus providing a stable angle.

Remove the insertion instruments.

Using the hexagonal screwdriver, align the end cap with the nail axis and fix it by means of the holding sleeve. 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 locking screw is fixed. The last turns will offer some resistance caused by a groove in the thread which prevents the screw from loosening. Tighten the end cap firmly.

Note: To minimize the chance of cross-threading, turn the end cap counterclockwise until the threads of the end cap align with the threads of the nail. Insert the end cap by turning clockwise until it is fully seated.

Alternative

The end cap can also be inserted after step 14 (page 18).



The spiral blade locking option with one Spiral Blade (450.882–892) and one Locking Screw \emptyset 6.0 mm (450.862–872) is used for patients with an osteoporotic bone structure and/or extensive and complex supra-condylar comminuted fracture areas. The increased purchase area of the blade provides an optimized load distribution in the condyles and improves fixation of the distal fragment thus decreasing the risk of nail protrusion into the knee joint.

Perform steps 1 to 10 as described on pages 4 to 15.

11 Mount aiming arm and insert locking screw

Attach the Aiming Arm for Spiral Blade Locking (357.116) to the insertion handle. Insert the turquoise triple trocar assembly (Protection Sleeve 11.0/8.0 (357.118), Drill Sleeve 8.0/4.9 (357.097) and Trocar \emptyset 4.9 mm (357.098)) through the cranial hole of the aiming arm and, after a stab incision, to the bone. Remove the trocar.

Drilling, length measuring, and insertion of the Locking Screw Ø 6.0 mm are performed as described in steps 12 and 13 on pages 17 and 18.



12 Insert double-sleeve combination

Insert the pink double-sleeve combination (Protection Sleeve 15.0/13.0 (357.123) and Drill Sleeve 13.0/3.2 (357.124)) through the caudal hole on the aiming arm. Make a stab incision and advance the combination to the lateral cortex.



13 Insert guide wire and measure length for spiral blade

Insert the calibrated Guide Wire Ø 3.2 mm (357.129) into the condyles until its tip is flush with the medial cortex. Confirm wire position radiographically. Make sure the drill sleeve is in contact with the bone and read the length for the spiral blade from the guide wire. Remove the drill sleeve.



14 Open cortex

Insert the Drill Bit Ø 13.0 mm (351.270) over the guide wire through the protection sleeve and open the lateral cortex manually or with a power tool. The drill bit should open the lateral cortex only to prepare the seat of the spiral blade head. The automatic stop prevents the drill bit from penetrating too far. Remove the drill bit and protection sleeve.



15 Attach spiral blade to spiral inserter

Assemble the spiral blade insertion instruments using the Connecting Screw for Spiral Blades (357.132) and the Spiral Inserter (357.120). Attach the spiral blade of the previously determined length firmly to the spiral inserter.



16 Insert spiral blade

Bring the spiral blade and the spiral inserter over the guide wire through the aiming arm and to the bone. Insert the blade manually or by gentle hammer taps to the connecting screw attached to the spiral inserter. 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.



17 Proximal locking

Perform the proximal locking as described in steps 15 to 18 on pages 19 and 21.

18 Insert end cap

The use of the pink End Cap for Spiral Blade (451.895) is mandatory. It fulfills two functions: It prevents bone ingrowth into the nail and locks the spiral blade proximally providing a stable angle. The end cap presses against the edge of the spiral blade preventing it from backing out.

Remove the insertion instruments.

Using the hexagonal screwdriver, align the end cap with the nail axis and fix it by means of the holding sleeve. 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. The last turns will offer some resistance caused by a groove in the thread which prevents the screw from loosening. Tighten the end cap firmly.

Alternative

The end cap can also be inserted after step 16.



1 Remove end cap

Remove the ingrown tissue from the hexagonal recess of the end cap and the locking implants. Unscrew the end cap using the Hexagonal Screwdriver (314.750).



2 Remove the most distal locking implant

Remove the most distal locking implant (locking screw \varnothing 6 mm or spiral blade).

Locking screw \emptyset 6 mm: unscrew the locking screw using the Hexagonal Screwdriver (314.750) and Holding Sleeve (314.280).

Spiral blade: screw the Extraction Screw for Spiral Blade (357.360) into the blade head and screw the Hammer Guide (357.117) onto the extraction screw. Knock the spiral blade out with the Slide Hammer (357.026).

Note: Before removing the last locking screw, thread the connecting screw into the distal end of the nail. This will prevent the nail from rotating in the medullary canal.



3 Remove locking bolts

Unscrew the locking bolts using the Hexagonal Screwdriver (314.750). If the bolts cannot be unscrewed because the thread no longer grips the bone, use the Holding Sleeve (314.280).



4

Mount hammer guide

Before removing the last locking implant, screw the Extraction Screw for DFN (357.133) into the distal end of the nail and tighten with the Pin Wrench (321.170). The last locking implant prevents the nail from rotating or sliding away.

Screw the Hammer Guide (357.117) onto the extraction screw for DFN and tighten.

Alternative

If the extraction screw for DFN is not available, the hammer guide can be screwed directly into the distal end of the nail.



5 Remove last locking implant

Unscrew the last locking implant using the Hexagonal Screwdriver (314.750) and, if necessary, the Holding Sleeve (314.280).



6 Remove nail

Knock the nail out with gentle blows of the slide hammer.



Cleaning of instruments

Proper functioning of the instruments can be maintained by careful cleaning.

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.



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Not all products are currently available in all markets.

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