TNAdvanced™
TIBIAL NAILING SYSTEM

Infrapatellar Approach

Surgical Technique

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

AO approved by AO Technical Commission

Image intensifier control

For detailed cleaning and sterilization instructions, please refer to
www.depuysynthes.com/hcp/cleaning-sterilization
or sterilization instructions, if provided.

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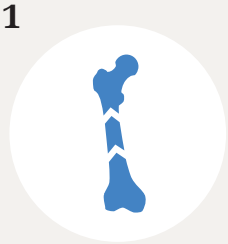
The AO Principles of Fracture Management

Mission
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

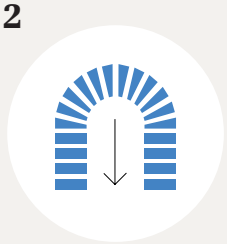
AO Principles [1,2]

1



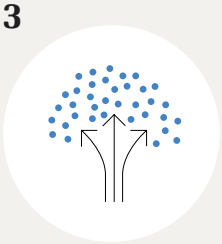
Fracture reduction and fixation to restore anatomical relationships.

2



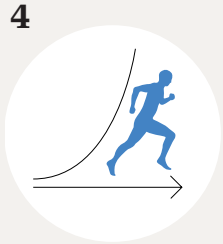
Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

3



Preservation of the blood supply to soft-tissues and bone by gentle reduction techniques and careful handling.

4



Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

[1] Müller ME, M Allgöwer, R Schneider, H Willenegger. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991
[2] Buckley RE, Moran CG, Apivatthakakul T. AO Principles of Fracture Management: 3rd ed. Vol. 1: Principles, Vol. 2: Specific fractures. Thieme; 2017.

Indications

The Tibial Nail Advanced implants are intended for treatment of fractures in adults and adolescents (12-21) in which the growth plates have fused. Specifically, the implants are indicated for:

- Open and closed proximal and distal tibial fractures
- Open and closed tibial shaft fractures
- Tibial malunions and nonunions

Contraindications:
No contraindications specific to these devices.

Warnings

- It is critical to ensure proper selection of the implant meets the needs of the patient anatomy and the presenting trauma. Physician should consider reaming to avoid under-sizing, to improve fit of nail, and to accelerate bone healing.
- Use of these devices is not recommended when there is systemic infection, infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Physician should consider patient bone quality to ensure it provides adequate fixation to promote healing.
- Conditions that place excessive stresses on bone and implant such as severe obesity or degenerative diseases, should be considered. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patients.
- Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopaedic implant.
- Physician should take into account an increase in medullary pressure occurring during medullary nailing or reaming. This releases varying amounts of bone marrow and fat into the venous blood system.

Opening the Tibia

1. Position patient

1A Position the patient supine on a radiolucent table. Ensure that the knee of the injured leg can be flexed at least 90°. Position the image intensifier such that visualization of the tibia including the articular surface proximally and distally is possible in AP and lateral views.

Optionally, the procedure can be performed on a fracture table with the leg placed in traction. The knee roller can be placed under the lower part of the thigh if it obstructs the view of the tibia plateau in AP view.

1A

1A

2. Reduce fracture

2A Perform closed reduction manually by axial traction under image intensifier.
2B The use of a large distractor may be appropriate in certain circumstances.

Note: **The reduction can be temporarily fixed with reduction clamps. In epiphyseal fractures, the condyles or the pilon are fixed first in order to enable the nail insertion.**

2B

3. Make incision

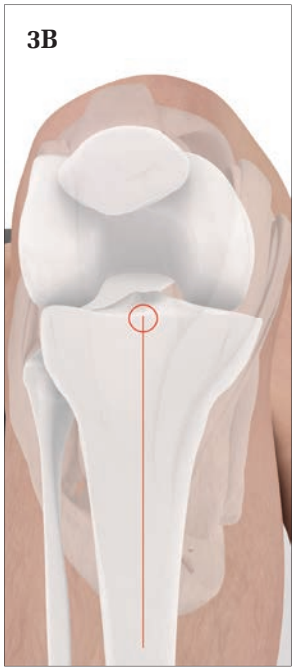
3A Make an incision in line with the central axis of the intramedullary canal. Depending on the anatomy of the patient, this incision can be transpatellar, medial or even lateral parapatellar.

3B The incision starts proximally at the distal third of the patella along the patellar ligament down to the tibial tuberosity.

3C Mobilise the infrapatellar fat pad laterally and dorsally without opening the synovium. A free access of the nail to the insertion point must be guaranteed.
Prepare the entry site of the nail on the ventral edge of the tibial plateau.

3A

3B



4. Determine entry point

Instruments	
03.010.500	Silicone Handle With Quick Coupling
03.043.003	Protection Sleeve
03.043.004	Wire Guide
03.045.018	Guide Wire

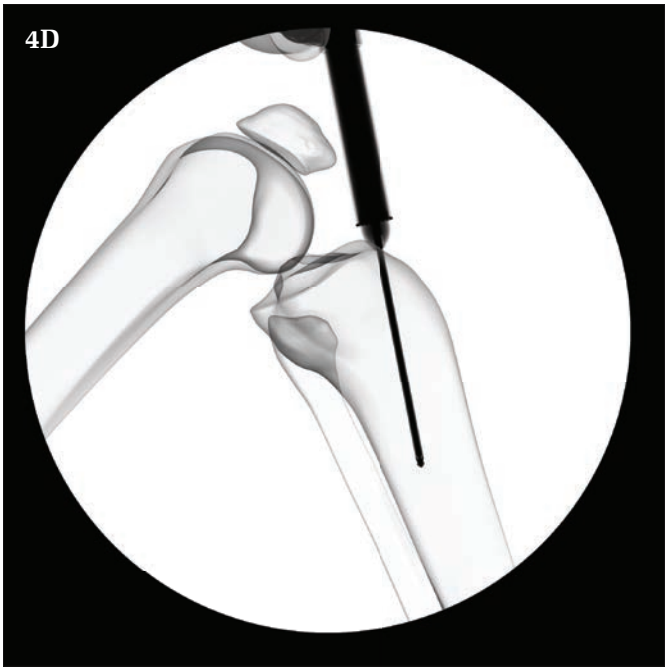
4A In the frontal view the entry point is in line with the axis of the intramedullary canal and with the lateral tubercle of the intercondylar eminence.

4B In the sagittal view the entry point is at the ventral edge of the tibial plateau

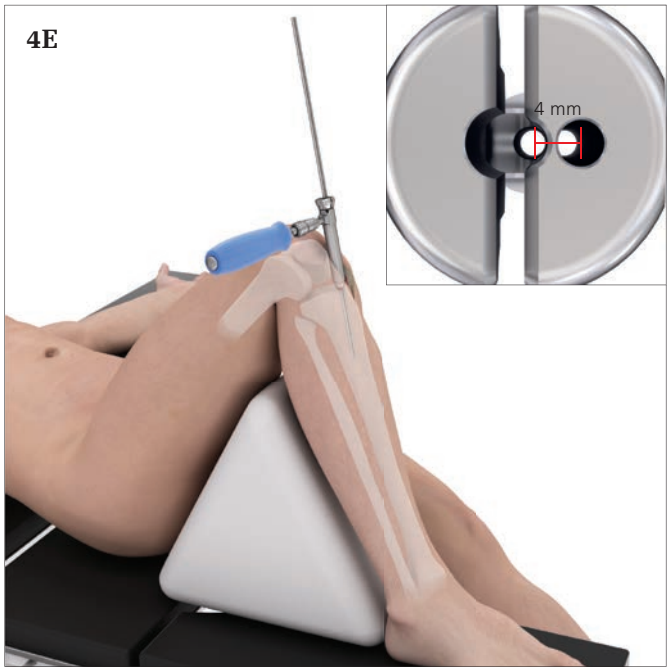
Precaution: **Deviation from the optimal entry portal may cause irreducible malalignment, iatrogenic bone and soft tissue damage, malunion, and nonunion.**

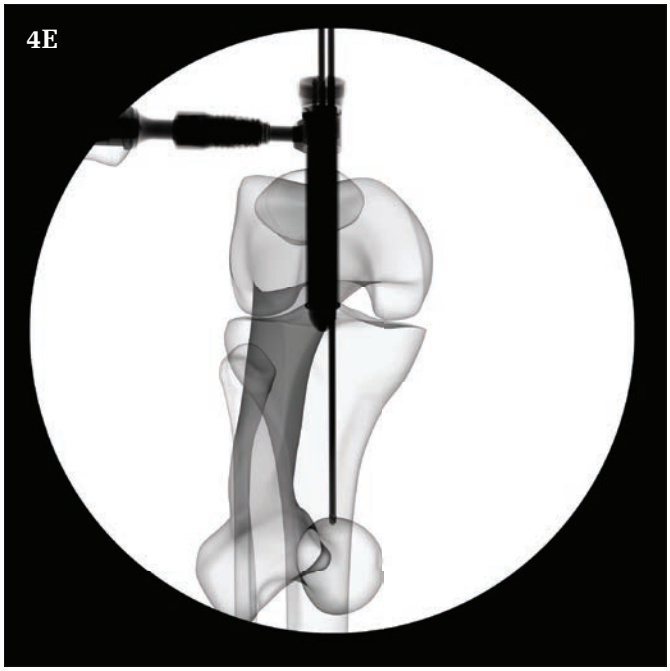
4C Attach the handle to the protection sleeve and assemble the wire guide inside the protection sleeve. Position the assembly over the insertion point.

4D Insert a guide wire through the wire guide into the bone to a depth of approximately 8 cm – 10 cm. Check the position under imaging in the AP and lateral views.

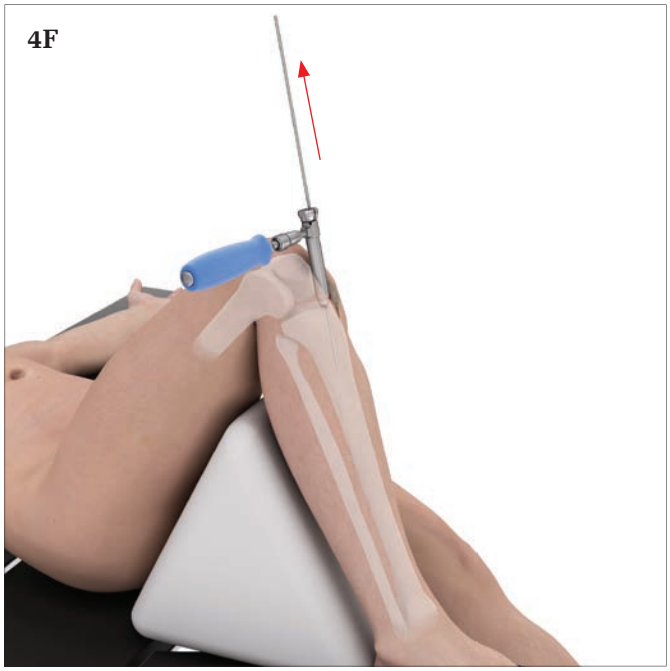


4E Adjustments to the guide wire location can be "dialed-in" by rotating the wire guide to place a second guide wire while the first guide wire remains in place.





4F After correct placement of the second guide wire, remove the initial, central guide wire.



5. Open medullary canal

Instruments

03.043.016 Drill Bit

5A Remove the wire guide from the protection sleeve and place the drill bit over the guide wire, through the protection sleeve, and down to the bone.

5B Use a protection sleeve to prevent damage to the surrounding soft tissue, monitor that the tip of the protection sleeve remains in direct contact to the proximal tibia.

5B

5C Drill to a depth of approximately 8 –10 cm.

Precaution: **Pay special attention not to penetrate the posterior cortex.**
5D Remove the drill bit and guide wire.

5D

5E When using 12 and 13 mm nails, the opening must be over-reamed by at least 1 mm using a medullary reamer system.

Precaution: **Do not start the drill inside the protection sleeve.**

Note: **Dispose of the guide wire. Do not reuse.**

6. OPTION: Reaming rod

Instruments	
03.010.495	IMN Reduction Tool
03.010.496	T-Handle With Quick Coupling
03.010.093	Rod Pusher
352.032	Reaming Rod, ∅ 2.5 mm, L 950 mm

6.OPT.A The use of a reaming rod can facilitate reduction, serve as a guide for intramedullary reamers, and aids in keeping bone fragments aligned during nail insertion.

Precaution: The Advanced Tibial Nail is cannulated and can be inserted over reaming rods with a diameter of up to 3.8 mm at their widest point. Compatible reaming rods will pass through the dedicated hole in the center of the aiming arm

6.OPT.B The IMN reduction tool may be used to aid in achieving alignment of the proximal and distal fragments, and for guiding the reaming rod into the distal fragment.

Insert the reduction finger to the desired depth.

6.OPT.A

6.OPT.B

6.OPT.C Pass the reaming rod through the cannulation of the instrument.

Remove the reduction IMN reduction tool.

Note: **Use the Rod pusher to help retain the reaming rod during the extraction of the reduction instrument.**

6.OPT.C

7. OPTION: Ream the medullary canal

Instruments	
352.032	Reaming Rod, ∅ 2.5 mm, L 950 mm

7.OPT.A If deemed appropriate, enlarge the medullary canal to the desired diameter using a DePuy Synthes reamer system intended for tibial reaming procedures by following the corresponding instructions of the reamer system.

7.OPT.B Check fracture reduction under image intensifier control.

Precaution: **Do not start the reamer inside the protection sleeve.**

Precaution: **Monitor that the tip of the protection sleeve remains in direct contact to the proximal tibia.**

Note: **Use the rod pusher (03.010.093) to prevent the reaming rod from backing off.**

8. Determine nail length

Instruments	
03.045.035	Direct Measuring Device
03.045.036	Elongation Tube

8A The nail length is determined either radiographically or over the reaming rod.

8B To measure nail length over the reaming rod, confirm reaming rod insertion depth under image intensification and account for a possible distraction or shortening ot the fracture site.

8C Assemble to direct measuring device and elongation tube and pass the assembly over the reaming rod and down to the nail entry point.

8D Read the nail length directly from the measuring device.

8E The measuring scale is calibrated to the total length of a 950 mm reaming rod. When using a 1150 mm reaming rod, the length is indicated by the etched line on the reaming rod.

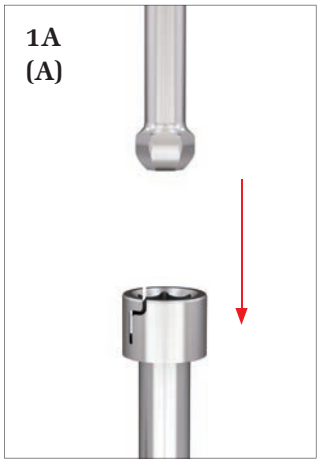
8F The nail diameter is determined either by reaming (optional) or radiographically.

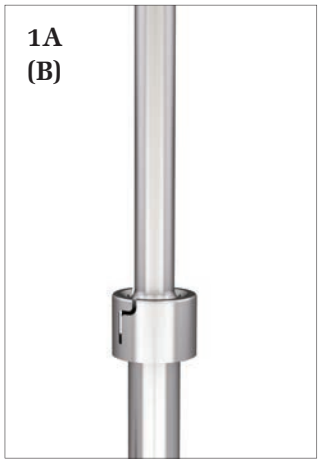
8D

1. Assemble insertion instruments

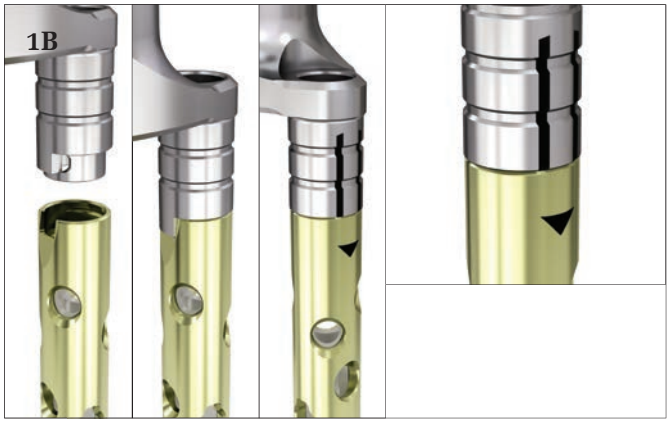
Instruments	
03.043.018	Insertion Handle
03.043.019	Connecting Screw
03.043.027	T-Handle Ball Hex Screwdriver

1A Connect the hexagonal ball at the tip of the screwdriver to the recess of the connecting screw by pushing both parts together until they snap into place and the connecting screw is retained to the screwdriver.





1B Connect the insertion handle to the nail by aligning the markings on the nail with the two slots on the barrel of the insertion handle. Push both parts together until they snap into place. The connection is designed to hold the nail in place until the connecting screw is tightened.



1C Pass the connecting screw through the insertion handle to engage with the nail and securely tighten it with the screwdriver. Remove the screwdriver.

Precaution: **Ensure that the connection between the nail and the insertion handle is tight. Retighten if necessary, after hammering and prior to the attachment of the aiming arm.**

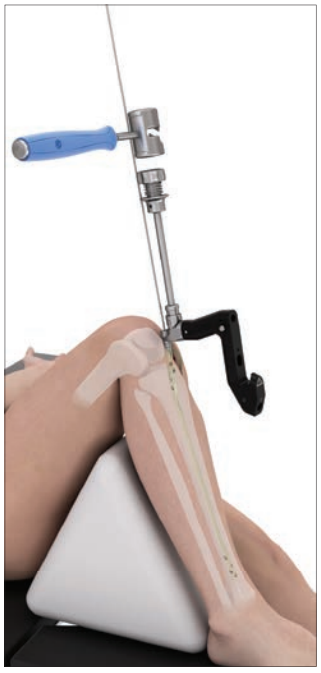
Precaution: **Do not attach the aiming arm to the insertion handle at this point.**

2. Insert nail

Instruments	
03.010.522	Hammer
03.043.028	Driving cap
03.043.027	T-Handle Ball Hex Screwdriver
03.010.170	Hammer guide

2A Remove the protection sleeve.

2B Hyperflex the knee to aid nail insertion into the medullary canal, and insert the nail into the intramedullary canal.



2C Monitor the nail passage across the fracture; control in two planes to avoid malalignment.
Insert the nail until it is at or below the tibial opening.
Check final nail position in AP and lateral views.

Precaution: To use the hammer, attach the driving cap to the insertion handle and secure it by twisting it one quarter turn. Apply light and controlled hammer blows to seat the nail.

Note: The hammer guide may aid in controlling the direction of the hammer blows. Therefore, the hammer guide can be attached to the back end of the drive cap by screwing both parts together.

Note: After using the hammer, retighten the connecting screw to the nail with the screwdriver.

Note: If the nail needs to be backed out with a hammer, use the slotted hammer to slide along the bar of the driving cap or the hammer guide. Do not strike directly on the insertion handle as this will damage the handle.

Precaution: If insertion is difficult, use the C-arm to confirm that there is no obstruction of the medullary canal. If no obstruction is found, choose a nail with a smaller diameter or enlarge the entry canal by reaming the medullary canal to a larger diameter.

Precaution: Do not use excessive twisting motions of the insertion handle.

Precaution: Remove reaming rod.

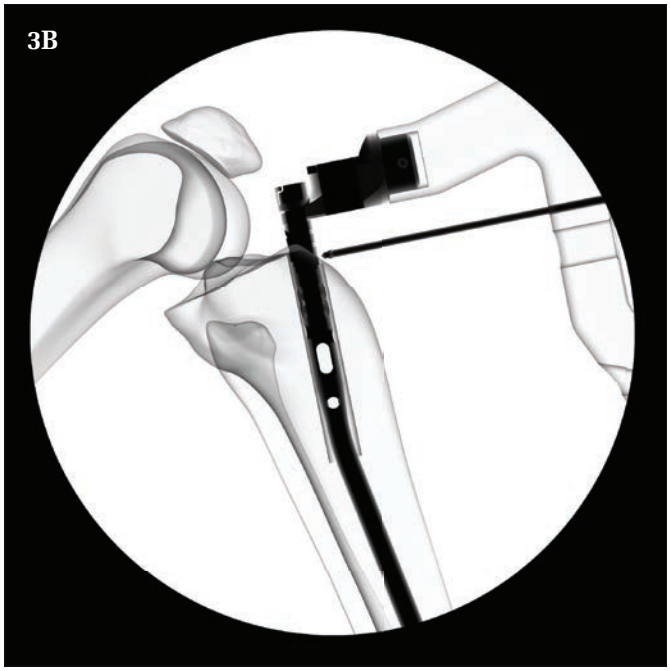
3. Check proximal nail position

Instruments	
03.043.029	Aiming Arm
03.045.018	Guide Wire ∅ 3.2 mm, with drill tip, length 400 mm

3A To check the insertion depth of the nail, insert a 3.2 mm guide wire through the hole in the insertion handle as shown in the illustration.

3B Check proximal nail position under image intensifier control in the lateral view.

The tip of the guide wire indicates the exact proximal position of the tibial nail.



3C At this point, the trajectories of the two most proximal locking screws can be projected on a C-arm image. Attach the aiming arm to the insertion handle, by sliding it into the hook at the distal part of the insertion handle (1) and then rotating the latch towards the insertion handle for both parts to connect (2).

Precaution: **The distance between the markings on the insertion handle is 5 mm and corresponds to the extensions of the end caps. This feature can be used for over-insertion of the nail or for correcting the nail location within the medullary canal.**

Precaution: **If primary compression or secondary dynamization is planned, it is recommended to over-insert the nail by at least 7 mm, which corresponds to the maximum distance between the positions in static and dynamic modes. Protrusion of the proximal end of the nail can lead to irritation of the patellar tendon.**

3D The trajectories of the two most proximal locking screws can be projected on a C-arm image by placing the drill bit 03.045.022 through the dedicated holes in the aiming arm. Insert the protection sleeve 03.045.019 and drill sleeve 03.045.020 into the corresponding hole in the aiming arm and assess the trajectory of the screw by taking an X-ray image in which the projections of the drill bit and the drill sleeve overlay.

3D

3E If the driving cap has been used, remove it now.

Remove the aiming arm, unless proximal locking is the next step.

3E

4. Check distal nail position

Instruments	
03.043.027	T-Handle Ball Hex Screwdriver

4A Check final nail position under image intensifier control in AP and lateral views.

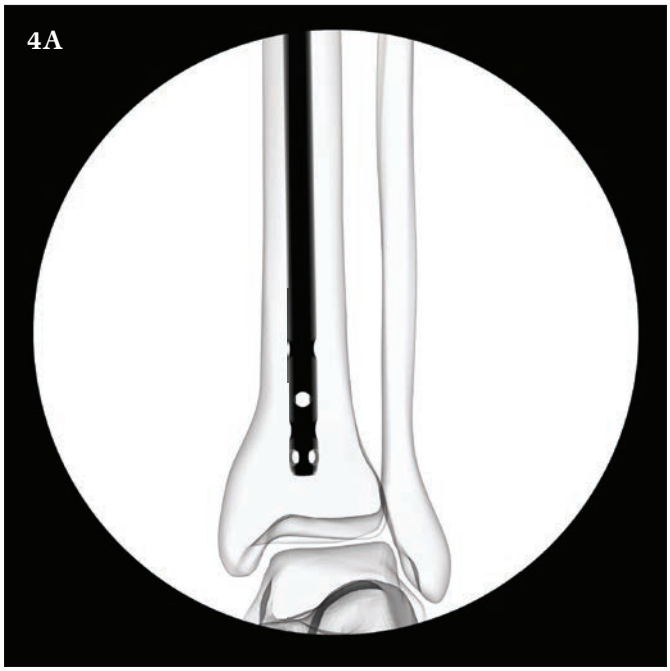
4B Ensure that the reaming rod has been removed.

Precaution: **Insertion depth is critical for distal third fractures where a minimum of two locking screws below the fracture line are required to stabilize the distal segment.**

4C Confirm that the nail is securely connected to the insertion handle, especially after hammering, using the screwdriver.

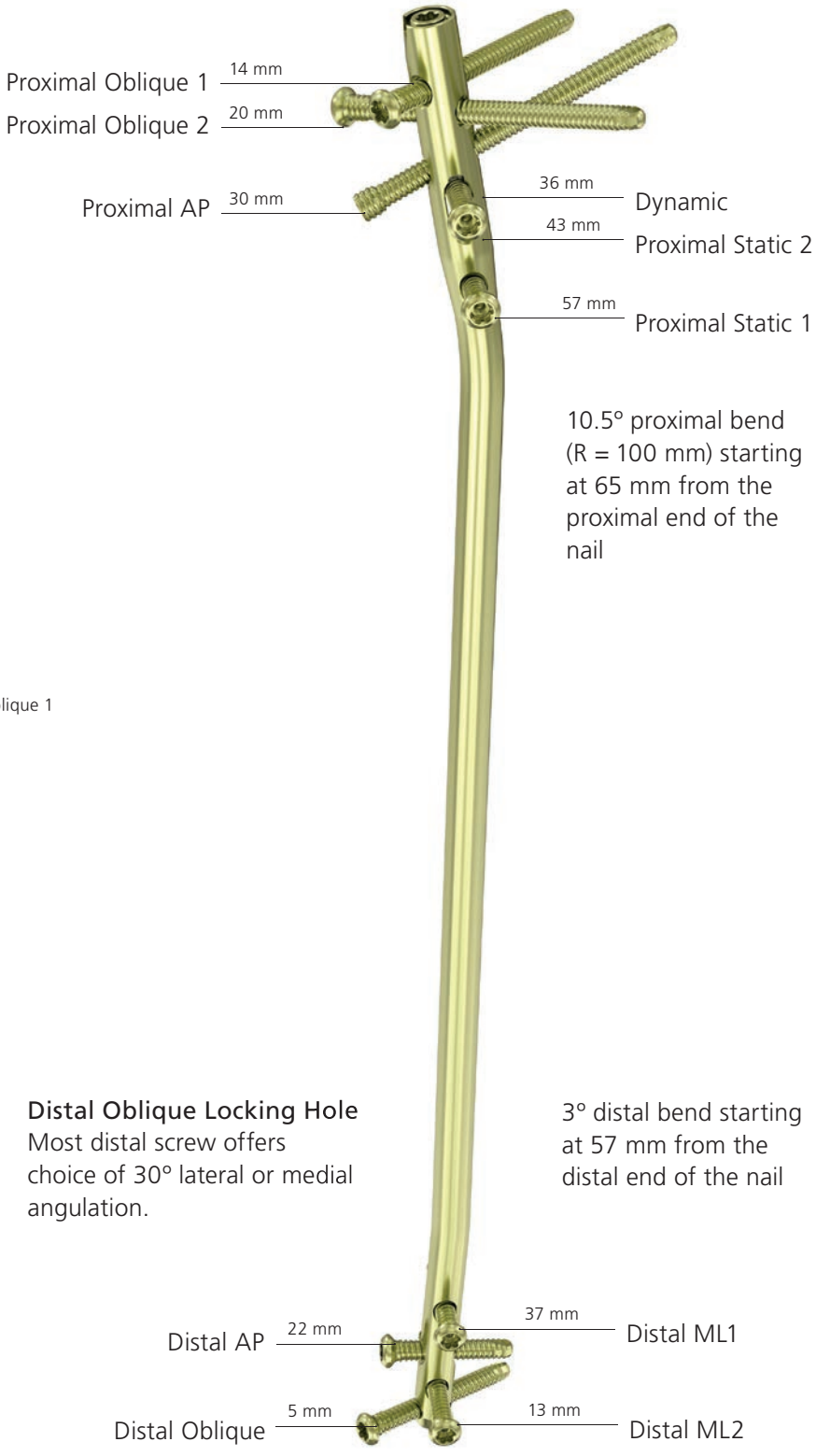
Precaution: **To achieve compression the tibial nail needs to be locked distally first. The tibial nail allows a maximum compression or dynamization of 7 mm.**

Precaution: **Depending on the fracture patterns it might be advantageous to lock proximally first.**



Locking Holes

Inlays made of polyetheretherketone (PEEK) in the nail provide angular stable locking in all screw holes, except for the Dynamic and Proximal Static 2 locking holes.



Distal Oblique Locking Hole
Most distal screw offers choice of 30° lateral or medial angulation.

1. Locking

Use the appropriate locking screws and drill bit for the nail diameter selected.

Nail Diameter	Locking Screw	Drill Bit
9 mm to 13 mm	5.0 mm (light green)	4.2 mm
8 mm	Proximal Locking: 5.0 mm (light green) Distal Locking: 4.0 mm (dark blue)	4.2 mm 3.2 mm

Distal and proximal locking of the nail may be performed in either order.

If using a backstroke technique to reduce fracture gaps, distal locking must be performed prior to proximal locking. The hammer guide is attached to the driving cap and insertion handle. Light reverse hammer blows may be used to compress the fracture; monitor reduction radiographically.

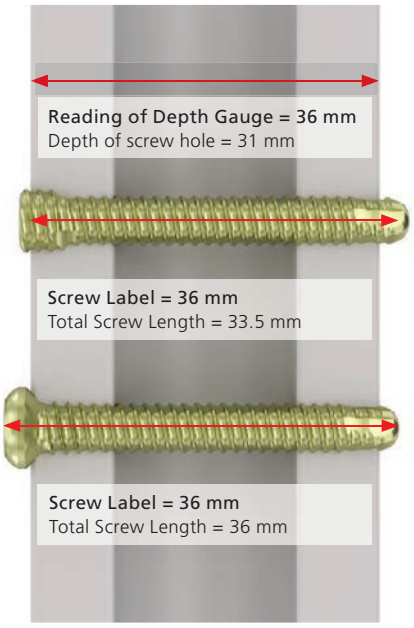
∅ 8 mm ∅ 9 mm ∅ 10 mm ∅ 11 mm ∅ 12 mm ∅ 13 mm

2. About measuring screw length

Screw length is measured by using either of two methods.

1. Read length from the calibrated drill bits
2. Measure length using depth gauge for locking screws

Readings do not reflect the measured distance, they indicate the required screw length. The reading on the scale will correspond to the screw length as indicated on the screw label, taking into account the amount of screw tip protrusion required to get full screw thread engagement in the far cortex.



Notes:

- **Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length.**
- **Beware depth gauges are implant specific. Always use the appropriate depth gauge as specified in the surgical technique guide.**

Precaution: Select adequate screw length to avoid protrusion of the screw tips and irritation of soft tissue.

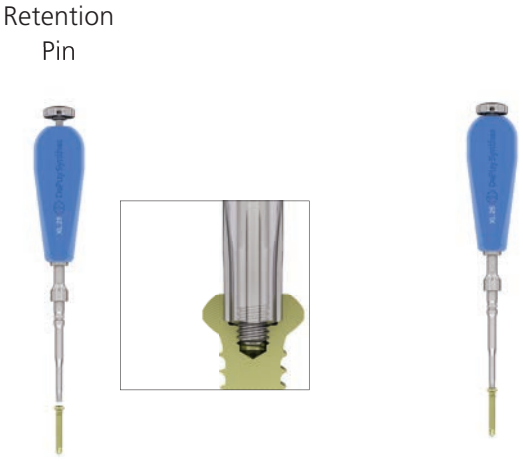
3. Screw options

Tibial Nail Advanced offers two different types of screws:

1. Locking Screw
   Standard IM nail locking screw.

2. Low Profile Locking Screw
   The low profile screw has been designed to reduce implant prominence in places with minimal soft tissue coverage.

Note: **Both types of screws have a threaded recess and can be securely attached to the screwdriver by using the retention pins. To do so, slide the retention pin through the back of the screwdriver until it stops. Further advance it by turning it clock-wise, until its tip extends out of the tip of the screwdriver.**

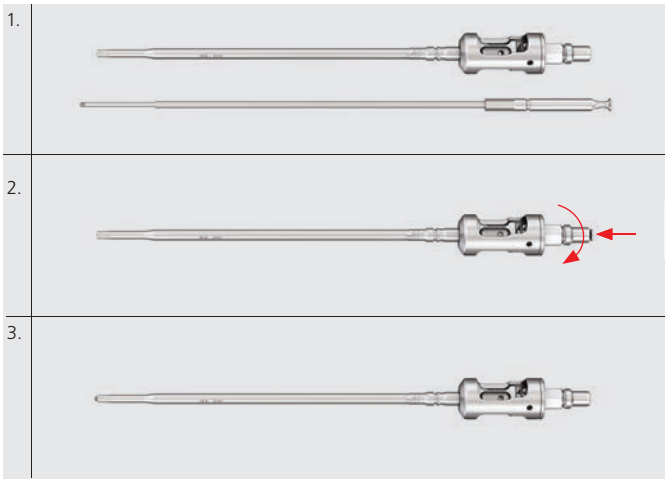


Engage the screwdriver in the recess of the locking screw and thread the retention pin into the screw's recess to lock the screw to the screwdriver.

Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft with its retention pin, following the same steps as described above.

Precaution: **The screw must not be tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position.**

Note: **Both types of screws have a threaded recess and can be securely attached to the screwdriver by using the retention pins (1.). To do so, slide the retention pin through the back of the screwdriver until it stops (2.). Further advance it by pushing it through, until it clicks into place and its tip extends out of the tip of the screwdriver (3.).**



4. OPTION: Low Profile Screw

4.OPT.A The low profile screw can be used instead of the standard locking screw, by following the same basic steps for screw insertion.

4.OPT.A
Low Profile
Locking Screw

4.OPT.B An optional sleeve is available to indicate when the screw is fully seated. Slide it over the tip of the screwdriver until it locks in place.

4.OPT.B

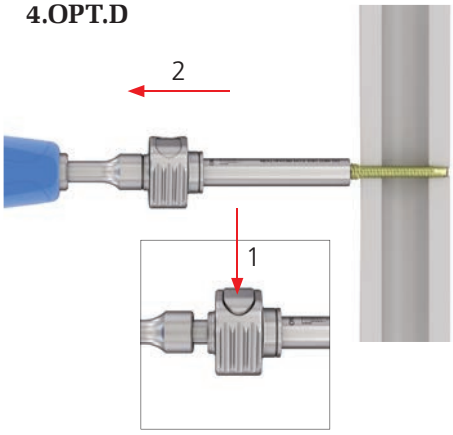
4.OPT.C In its initial position, it will cover the head of the screw, protecting surrounding soft tissues from the screw head's cutting flutes. Advance the screw until the sleeve touches the cortex.

Note: **pay attention not to damage the cortex with the sleeve**

4.OPT.C

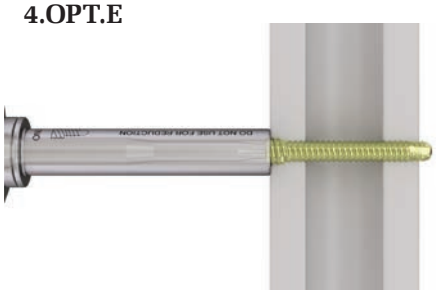
4.OPT.D Then retract the sleeve by pushing the release button and pulling it backwards towards the screwdriver handle.

4.OPT.D



4.OPT.E Continue to advance the screw, now sinking the threaded screw head into the bony cortex. Once the sleeve touches the cortex a second time, the screw head will be 0.5 mm proud of the cortex.

4.OPT.E



4.OPT.F The cutting flutes in the 5 mm low profile screw's threaded head are designed to allow insertion of the screw without any extra steps. However, in hard bone it is recommended to enlarge the near cortex with the ∅ 5.5 mm reamer, to make room for the screw head, and avoid excessive insertion torque.

Note: **All nails require 5 mm screws, except for the 8 mm nail in its distal holes. Locking the distal portion of the 8 mm nail requires 4 mm screws.**

Note: **4 mm locking screws cannot be attached to the screwdriver with the retention pin**

Note: **Prior to insertion of the 4 mm low profile screws, the use of the ∅ 5.5 mm reamer is mandatory**

4.OPT.F

Distal Locking

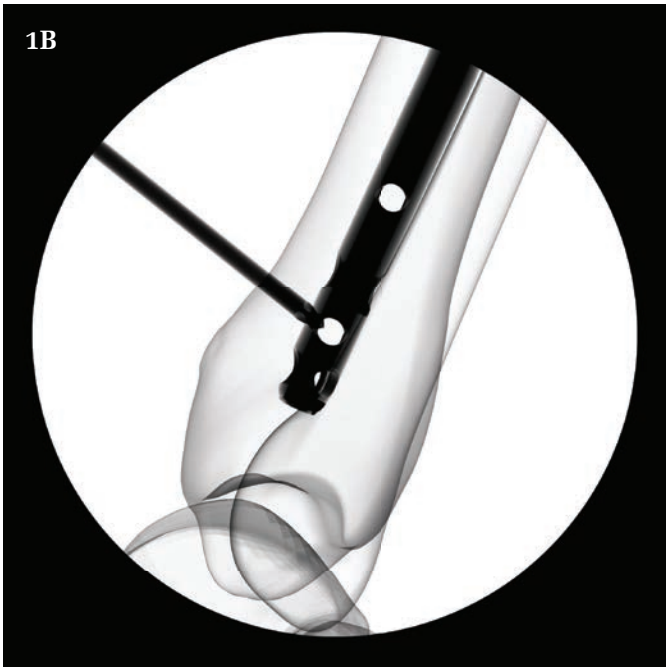
For distal third fractures a minimum of two locking screws are required to stabilize the distal segment, and the use of the most distal locking option is recommended. This locking option is oriented 30° from the sagittal plane.

The most distal screw hole allows placing the screw at an angle of 30° from the sagittal plane in either medial or lateral direction.

1. Drill for distal locking

Nail Diameter	Locking Screw	Drill Bit
9 mm to 13 mm	5.0 mm (light green)	4.2 mm 03.010.104
8 mm	Distal Locking: 4.0 mm (dark blue)	3.2 mm 03.010.103

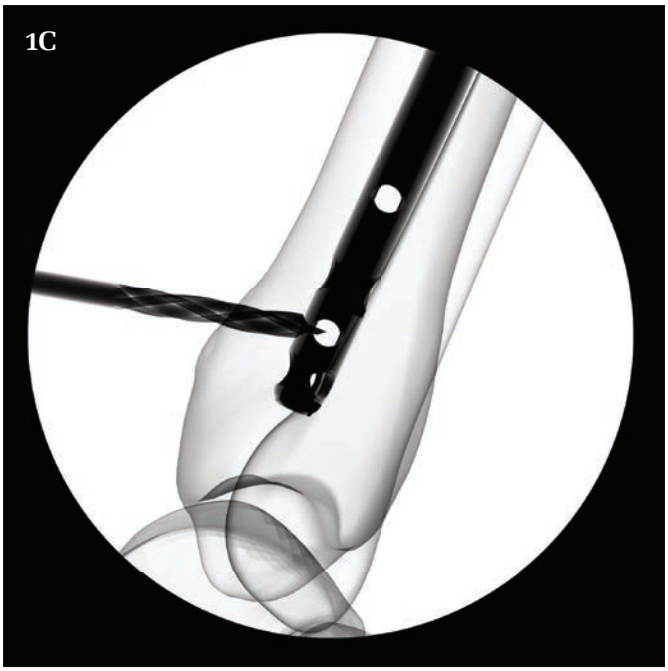
1A Align image: Check the reduction, correct alignment of the fragments, and leg length before locking the nail. Align the c-arm with the hole in the nail closest to the fracture until a perfect circle is visible in the center of the screen. (Distal ML hole shown in illustration).



1B Determine incision point: Place a guide wire on the skin over the center of the hole to mark the incision point and make a stab incision. Insert the tip of the appropriate drill bit through the incision and down to the bone.

1C Drill: Use the image intensifier to position the tip of the drill bit over the center of the locking hole. Incline the drill bit so that it aligns with the axis of the beam of the image intensifier. Hold the drill bit in this position and drill through both cortices.

Precaution: **Stop drilling immediately after penetrating both cortices.**



ALTERNATIVE: Alternative instrument to drill for distal locking

Instruments	
511.300	Radiolucent Drive (separately available)

Nail Diameter	Locking Screw	Drill Bit
9 mm to 13 mm	5.0 mm (light green)	4.2 mm 03.010.101
8 mm	Distal Locking: 4.0 mm (dark blue)	3.2 mm 03.010.100

1.ALT.A Alternatively, a radiolucent drive may be used for distal locking, following the same basic steps. The radiolucent drive enables the use of the image intensifier to ensure proper alignment of the drill with the locking hole in the nail. The radiolucent drive requires a separate set of drill bits

2. Determine locking screw length for distal locking

Instruments	
03.010.429	Direct Measuring Device

2A Stop drilling immediately after both cortices and detach the drill bit from its coupling.

2B Under image intensifier control, ensure the correct position of the drill bit beyond the far cortex.

2C Place the direct measuring device onto the drill bit. Read the graduation of the measuring device at the end of the drill bit. This corresponds to the appropriate locking screw length.

ALTERNATIVE: Alternative instrument to determine locking screw length

Instruments	
03.019.017	Depth Gauge

2.ALT.A Measure the locking screw length using the depth gauge for locking screws. Ensure the outer sleeve is in contact with the bone and the hook grasps the far cortex.

2.ALT.B Read the locking screw length directly from the depth gauge at the back of the outer sleeve.

3. Insert locking screw

Instruments	
03.045.003	Screwdriver Short XL25
03.045.004	Retention Pin XL25

3A Insert the appropriate length locking screw using the screwdriver.

ALTERNATIVE: Alternative instrument to insert locking screw

Instruments	
03.045.007	Screwdriver Shaft Short XL25
03.045.008	Retention Pin
03.140.027	Handle With Quick Coupling

3.ALT.A Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft with its retention pin, following the same steps as described above.

Precaution: **The screw must not be tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position.**

3.ALT.A

ALTERNATIVE: Alternative low profile locking screw

Instruments	
03.045.010	Sleeve
03.045.029	Reamer ∅ 5.5 mm

3.ALT.2A The low profile screw can be used instead of the standard locking screw, by following the same basic steps for screw insertion.

3.ALT.2B An optional sleeve is available to indicate when the screw is fully seated. Slide it over the tip of the screwdriver until it locks in place.

3.ALT.2C The use of the ∅ 5.5 mm reamer, to make room for the threaded screw head, is recommended in hard bone.

Precaution: Use a ∅ 5.5 mm reamer, to make room for the threaded screw head of the 4.0 mm low profile locking screw for 8 mm nail.

3.ALT.2A

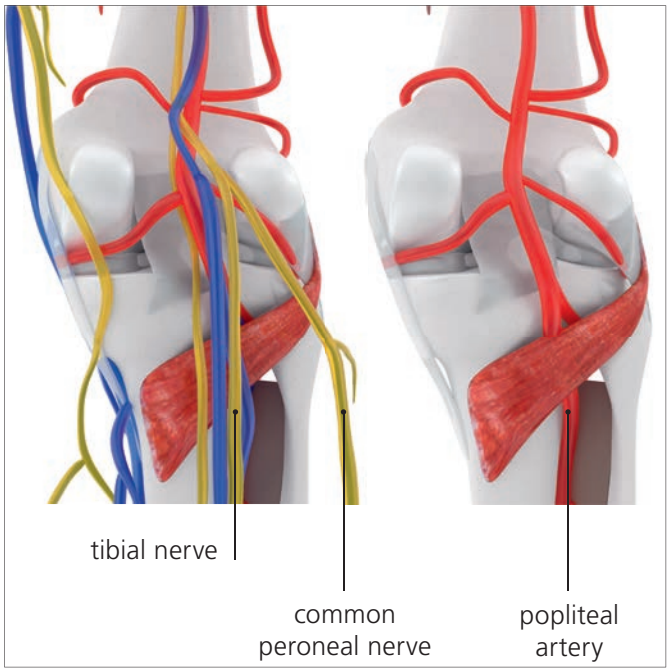
Low Profile
Locking Screw

Proximal Locking

Nail Diameter	Locking Screw	Drill Bit
All nails (8 mm to 13 mm)	5.0 mm (light green)	4.2 mm 03.045.022

Precaution (medial to lateral locking options): **Stop drilling immediately after penetrating both cortices.**

Precaution (oblique and AP locking options): **Proximal locking requires special attention. To avoid lesion of the popliteal artery, the tibial nerve and the common peroneal nerve, as well as damage to the proximal tibiofibular joint, drilling must be stopped immediately before penetrating the far cortex monitor the position of the drill bit.**



1. Mount aiming arm

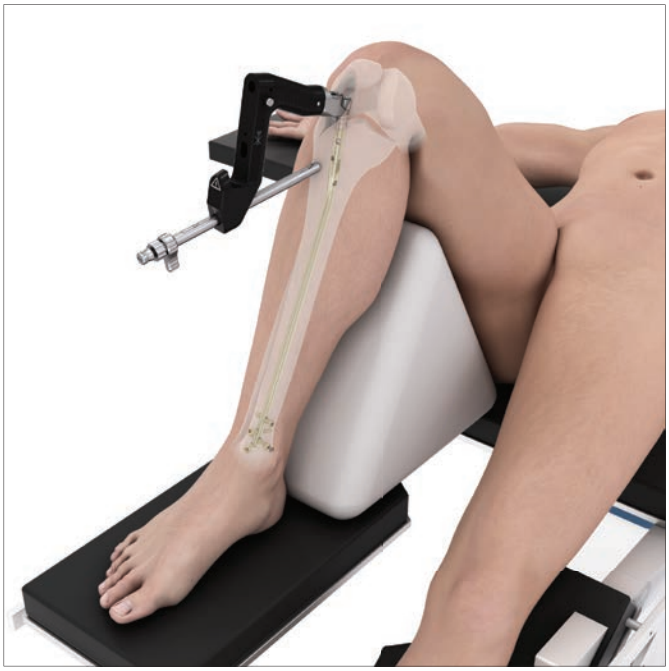
Instruments	
03.043.029	Aiming Arm
03.043.027	T-Handle Ball Hex Screwdriver

1A Confirm that the nail is securely connected to the insertion handle, especially after hammering, using the screwdriver 03.043.027.

1B Mount the aiming arm to the insertion handle.

Precaution: **Do not exert forces on the aiming arm, protection sleeve, drill sleeves and drill bits. These forces may prevent accurate targeting through proximal locking holes and damage drill bits.**

Note: **The proximal AP screw is inserted through the guiding hole in the insertion handle and does not require the aiming arm to be attached.**



2. Insert trocar assembly

Instruments	
03.045.019	Protection Sleeve
03.045.020	Drill Sleeve
03.010.070	Trocar ∅ 4.2 mm

2A Assemble the three-part trocar assembly (protection sleeve, drill sleeve, and trocar). Align the triangular marking at the tip of the protection sleeve with the marking beside the desired hole on the aiming arm, and insert the three-part trocar assembly through the aiming arm. Make a stab incision and insert the trocar to the bone. Twist the protection sleeve by a quarter turn to lock it into place. Remove the trocar.

3. Drill for proximal locking

Instruments	
03.045.022	4.2 mm Drill Bit

3A Ensure that the drill sleeve contacts the near cortex, insert the calibrated drill bit, start drilling the near cortex.

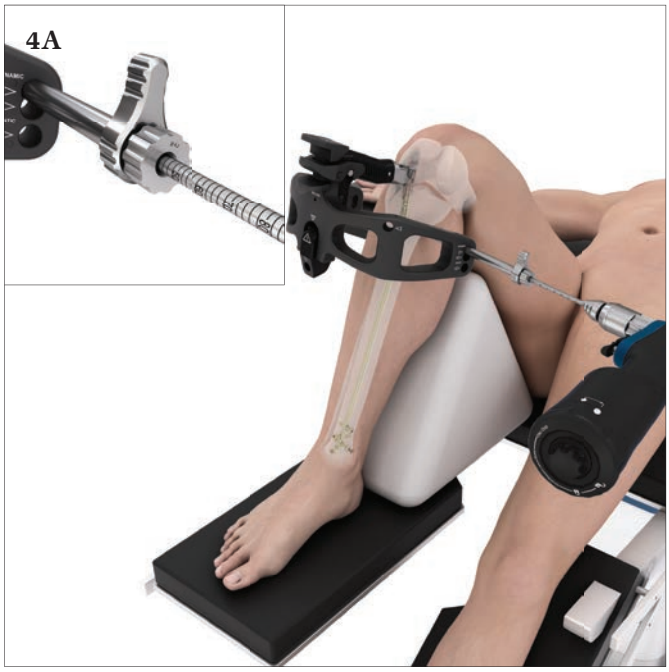
3B Drill to the desired depth and confirm drill bit position after drilling.

Precaution (medial to lateral locking options): Stop drilling immediately after penetrating both cortices.

Precaution (oblique and AP locking options): Proximal locking requires special attention. To avoid lesion of the popliteal artery, the tibial nerve, and the common peroneal nerve, as well as damage to the proximal tibiofibular joint, drilling must be stopped immediately before penetrating the far cortex. Monitor the position of the drill bit.

4. Measure screw length

4A Ensure that the drill sleeve contacts the bone and read the measurement from the calibrated drill bit at the back of the drill sleeve. This measurement indicates the appropriate length of the locking screw.



4B Remove the drill bit and the drill sleeve.

ALTERNATIVE: Alternative technique to determine locking screw length

Instruments

03.019.017	Depth Gauge

4.ALT.A After drilling, remove the drill bit and the drill sleeve.

4.ALT.B Insert the depth gauge into the protection sleeve. Make sure that the hook grasps the far cortex for bi-cortical screws or touches the end of the screw hole for mono-cortical screws, and that its sleeve is on the bone.

Read the measurement from the back of the depth gauge's sleeve, which indicates the appropriate length locking screw.

5. Insert locking screw

Instruments	
03.045.001	Screwdriver Long XL25
03.045.002	Retention Pin XL25

5A Insert the appropriate length locking screw using the screwdriver.

Precaution: **Select adequate screw length to avoid protrusion of the screw tip and irritation of soft tissue.**

5A

ALTERNATIVE: Alternative instrument to insert locking screw

Instruments	
03.045.005	Screwdriver Shaft Long XL25
03.045.006	Retention Pin
03.140.027	Handle With Quick Coupling

5.ALT.A Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft with its retention pin, following the same steps as described above.

5.ALT.A

Precaution: **The screw must not be tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position.**

5.ALT.B The shaft of the screwdriver has two lines, one of which indicates insertion depth of the locking screw (1), and the other indicating insertion depth of the low profile locking screw (2) relative to the tip of the protection sleeve. Screws are fully seated, when the line is flush with the head of the protection sleeve.

ALTERNATIVE: Alternative low profile locking screw

Instruments	
03.045.009	Sleeve
03.045.029	Reamer ∅ 5.5 mm

5.ALT.2A The low profile screw can be used instead of the standard locking screw, by following the same basic steps for screw insertion.

5.ALT.2B An optional sleeve is available to indicate when the screw is fully seated. Slide it over the tip of the screwdriver until it locks in place.
Before using the sleeve, unlock the protection sleeve, ensure it contacts the bone, and lock it into place again by twisting it a quarter turn.

5.ALT.2C The use of the ∅ 5.5 mm reamer, to make room for the screw head, is recommended in hard bone.

5.ALT.2A

6 OPTION: Compression locking mode

Instruments	
03.043.020	Compression Screw
03.043.027	T-Handle Ball Hex Screwdriver

6.OPT.A If the fracture gap needs compression after nail insertion, it can be accomplished without removing the insertion instruments. The nail allows a maximum compression of 7 mm.

6.OPT.B Distal locking is required prior to compression locking. Insert one proximal locking screw in the dynamic locking hole (DYNAMIC).

6.OPT.C Confirm that the nail is securely connected to the insertion handle using the screwdriver.

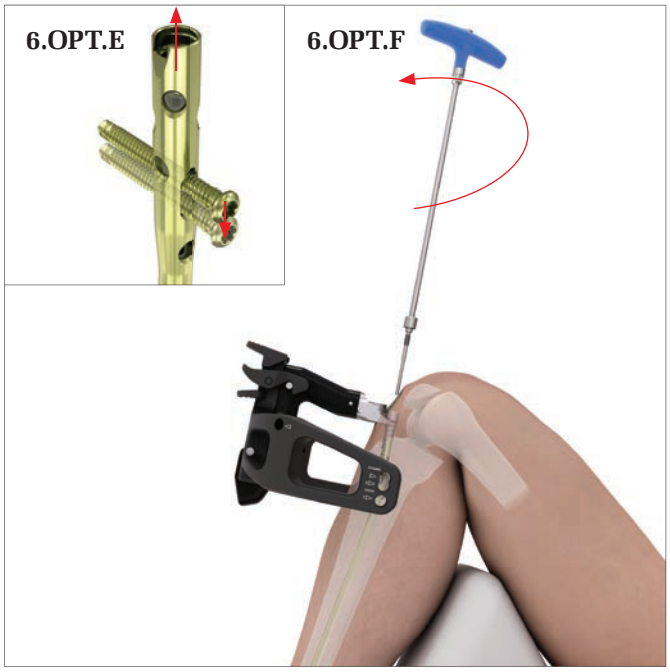
6.OPT.D Insert the compression screw through the connecting screw and into the nail using the screwdriver.

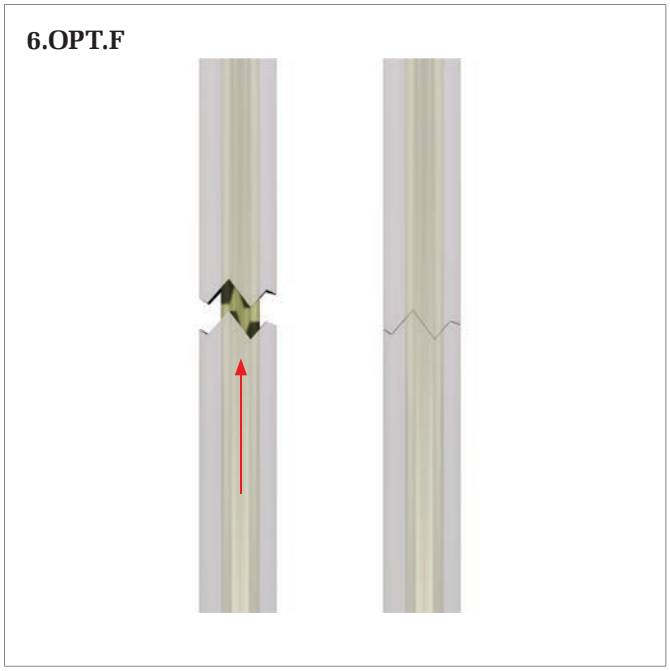
6.OPT.B

6.OPT.E The compression screw will contact the dynamic locking screw. Advance the compression screw until the fracture gap is reduced. Monitor reduction with the image intensifier.

6.OPT.F Each revolution of the compression screw corresponds to compression of 1 mm (maximum 7 mm). Control the fracture gap before, during, and after the compression procedure.

Note: **Do not overtighten the compression screw, it may deform the locking screw.**





6.OPT.G Secure the compression by inserting a second proximal locking screw in the most distal hole of the proximal locking options (STATIC 1).

6.OPT.H Remove the compression screw.

6.OPT.I Additional oblique locking screw can be inserted if required.

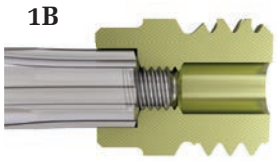
End Cap Insertion

1. Insert the end cap

Instruments	
03.045.001	Screwdriver Long XL25
03.045.002	Retention Pin XL25
03.043.027	T-Handle Ball Hex Screwdriver

1A Remove the aiming arm and the connecting screw. The insertion handle can remain in place to help align the end cap to the top of the nail. The end cap fits through the barrel of the insertion handle.

1B If desired, the end cap can be locked to the screwdriver by use of the retention pin. To do so, slide the retention pin through the back of the screwdriver until it stops. Further advance it by turning it clock-wise, until its tip extends out of the tip of the screwdriver.



1C Insert the end cap through the barrel of the insertion handle and tighten it to the nail.

Implant Removal

Implant removal is an optional procedure.

1. Remove end cap and locking screws

Instruments	
03.045.001	Screwdriver Long XL25
03.045.002	Retention Pin XL25

Clear the recess of the end cap and the locking screws of any tissue ingrowth. Remove the end cap with the screwdriver.

Note: **The screwdriver (without the retention pin) will fit over a 1.6 mm k-wire (e.g. 292.655), which may be used to guide the screwdriver into the recess of the end cap. Once the tip of the screwdriver engaged with the recess of the end cap, the k-wire is removed though the back end of the screwdriver, and the retention pit can be used to secure the end cap to the screwdriver.**

Remove all locking screws except one of the proximal locking screws with the screwdriver. Always remove the two most proximal locking screws in order to insert the extraction screw into the proximal end of the nail.

Note: **The XL25 recess is compatible with Stardrive® SD25 screwdrivers.**

2. OPTION: Additional Instruments for Screw Removal

Instruments	
03.045.030	Extractor Shaft for XL25 and SD25
03.045.031	Curette for XL25
03.045.032	Extraction Screw, conical
03.900.001	Sharp Hook, straight, length 150 mm

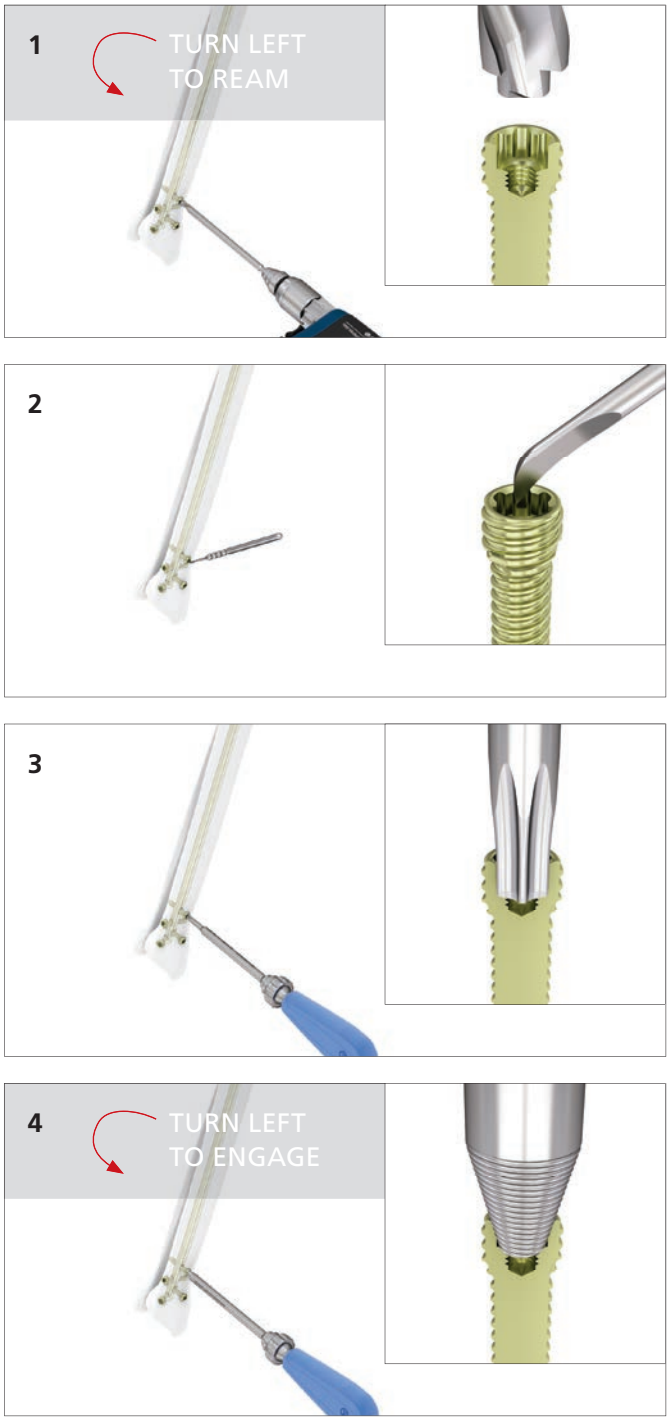
If screw heads are overgrown or the recess is damaged, additional instruments are available for screw removal. They can be used with all XL25 screw types.

1. Clear recess and screw head with the curette. The curette turns counter-clockwise

2. Use the sharp hook to clean out any remaining tissue

3. Engage the extractor shaft to remove the screw

4. If 3. does not work, use the conical extraction screw to remove the screw. The conical extraction screw turns counter-clockwise



3. Attach extraction screw and hammer guide

Instruments

03.010.000	Extraction Screw, for Tibial and Femoral Nails
03.010.170	Hammer Guide
03.045.001	Screwdriver Long XL25
03.045.002	Retention Pin XL25

Before removing the final locking screw, screw the extraction screw into the tibial nail and tighten it to prevent rotation or displacement of the nail posteriorly below the tibial plateau.

Attach the hammer guide to the extraction screw.

Remove the remaining locking screw with the screwdriver.

4. Remove nail

Instruments

03.010.522	Hammer

Extract the nail by applying gentle blows with the hammer.

Implants

Tibial Nail Advanced

Devices in scope

Tibial Nail Advanced

Length (mm)	∅ 8 mm	∅ 9 mm	∅ 10 mm
255	04.043.005S	04.043.105S	04.043.205S
270	04.043.010S	04.043.110S	04.043.210S
285	04.043.015S	04.043.115S	04.043.215S
300	04.043.020S	04.043.120S	04.043.220S
315	04.043.025S	04.043.125S	04.043.225S
330	04.043.030S	04.043.130S	04.043.230S
345	04.043.035S	04.043.135S	04.043.235S
360	04.043.040S	04.043.140S	04.043.240S
375	04.043.045S	04.043.145S	04.043.245S
390	04.043.050S	04.043.150S	04.043.250S
405	04.043.055S	04.043.155S	04.043.255S
420	04.043.060S	04.043.160S	04.043.260S
435	04.043.065S	04.043.165S	04.043.265S
450	04.043.070S	04.043.170S	04.043.270S
465	04.043.075S	04.043.175S	04.043.275S

Length (mm)	∅ 11 mm	∅ 12 mm	∅ 13 mm
255	04.043.305S	04.043.405S	04.043.505S
270	04.043.310S	04.043.410S	04.043.510S
285	04.043.315S	04.043.415S	04.043.515S
300	04.043.320S	04.043.420S	04.043.520S
315	04.043.325S	04.043.425S	04.043.525S
330	04.043.330S	04.043.430S	04.043.530S
345	04.043.335S	04.043.435S	04.043.535S
360	04.043.340S	04.043.440S	04.043.540S
375	04.043.345S	04.043.445S	04.043.545S
390	04.043.350S	04.043.450S	04.043.550S
405	04.043.355S	04.043.455S	04.043.555S
420	04.043.360S	04.043.460S	04.043.560S
435	04.043.365S	04.043.465S	04.043.565S
450	04.043.370S	04.043.470S	04.043.570S
465	04.043.375S	04.043.475S	04.043.575S

End Cap for Tibial Nail Advanced

Article No.	Extension (mm)
04.045.850S	0
04.045.855S	5
04.045.860S	10
04.045.865S	15

Locking Screw for Medullary Nails, ∅ 4 mm*

Article No.	Length (mm)	Article No.	Length (mm)
04.045.218	18	04.045.250	50
04.045.220	20	04.045.252	52
04.045.222	22	04.045.254	54
04.045.224	24	04.045.256	56
04.045.226	26	04.045.258	58
04.045.228	28	04.045.260	60
04.045.230	30	04.045.262	62
04.045.232	32	04.045.264	64
04.045.234	34	04.045.266	66
04.045.236	36	04.045.268	68
04.045.238	38	04.045.270	70
04.045.240	40	04.045.272	72
04.045.242	42	04.045.274	74
04.045.244	44	04.045.276	76
04.045.246	46	04.045.278	78
04.045.248	48	04.045.280	80

Locking Screw for Medullary Nails, Low Profile, ∅ 5 mm*

Article No.	Length (mm)	Article No.	Length (mm)
04.045.326	26	04.045.362	62
04.045.328	28	04.045.364	64
04.045.330	30	04.045.366	66
04.045.332	32	04.045.368	68
04.045.334	34	04.045.370	70
04.045.336	36	04.045.372	72
04.045.338	38	04.045.374	74
04.045.340	40	04.045.376	76
04.045.342	42	04.045.378	78
04.045.344	44	04.045.380	80
04.045.346	46	04.045.382	82
04.045.348	48	04.045.384	84
04.045.350	50	04.045.386	86
04.045.352	52	04.045.388	88
04.045.354	54	04.045.390	90
04.045.356	56	04.045.395	95
04.045.358	58	04.045.400	100
04.045.360	60		

Locking Screw for Medullary Nails, ∅ 5 mm*

Article No.	Length (mm)	Article No.	Length (mm)
04.045.026	26	04.045.062	62
04.045.028	28	04.045.064	64
04.045.030	30	04.045.066	66
04.045.032	32	04.045.068	68
04.045.034	34	04.045.070	70
04.045.036	36	04.045.072	72
04.045.038	38	04.045.074	74
04.045.040	40	04.045.076	76
04.045.042	42	04.045.078	78
04.045.044	44	04.045.080	80
04.045.046	46	04.045.082	82
04.045.048	48	04.045.084	84
04.045.050	50	04.045.086	86
04.045.052	52	04.045.088	88
04.045.054	54	04.045.090	90
04.045.056	56	04.045.095	95
04.045.058	58	04.045.100	100
04.045.060	60		

Locking Screw for Medullary Nails, Low Profile, ∅ 4 mm*

Article No.	Length (mm)	Article No.	Length (mm)
04.045.518	18	04.045.550	50
04.045.520	20	04.045.552	52
04.045.522	22	04.045.554	54
04.045.524	24	04.045.556	56
04.045.526	26	04.045.558	58
04.045.528	28	04.045.560	60
04.045.530	30	04.045.562	62
04.045.532	32	04.045.564	64
04.045.534	34	04.045.566	66
04.045.536	36	04.045.568	68
04.045.538	38	04.045.570	70
04.045.540	40	04.045.572	72
04.045.542	42	04.045.574	74
04.045.544	44	04.045.576	76
04.045.546	46	04.045.578	78
04.045.548	48	04.045.580	80

Alternatively, the Tibial Nail Advanced implants can be applied using associated instrumentation and a set of the following compatible screw implants:

Locking Screw Stardrive® ∅ 5 mm (light green)*

Article No.	Length (mm)	Article No.	Length (mm)
04.005.516	26	04.005.548	58
04.005.518	28	04.005.550	60
04.005.520	30	04.005.552	62
04.005.522	32	04.005.554	64
04.005.524	34	04.005.556	66
04.005.526	36	04.005.558	68
04.005.528	38	04.005.560	70
04.005.530	40	04.005.562	72
04.005.532	42	04.005.564	74
04.005.534	44	04.005.566	76
04.005.536	46	04.005.568	78
04.005.538	48	04.005.570	80
04.005.540	50	04.005.575	85
04.005.542	52	04.005.580	90
04.005.544	54	04.005.585	95
04.005.546	56	04.005.590	100

Materials

Device(s)	Material(s)	Standard(s)
Nails	Ti-6Al-4V (TAV) Titanium Alloy Polyetheretherketone (PEEK)	ISO 5832-3 ASTM F2026-17
End Caps	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11
Screws	Ti-6Al-7Nb (TAN) Titanium Alloy	ISO 5832-11

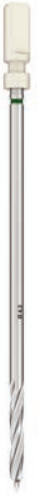
Locking Screw Stardrive® ∅ 4 mm (dark blue)*

Article No.	Length (mm)	Article No.	Length (mm)
04.005.408	18	04.005.440	50
04.005.410	20	04.005.442	52
04.005.412	22	04.005.444	54
04.005.414	24	04.005.446	56
04.005.416	26	04.005.448	58
04.005.418	28	04.005.450	60
04.005.420	30	04.005.452	62
04.005.422	32	04.005.454	64
04.005.424	34	04.005.456	66
04.005.426	36	04.005.458	68
04.005.428	38	04.005.460	70
04.005.430	40	04.005.462	72
04.005.432	42	04.005.464	74
04.005.434	44	04.005.466	76
04.005.436	46	04.005.468	78
04.005.438	48	04.005.470	80

*All screws available non-sterile or in sterile packaging. Corresponding sterile article number with suffix "TS" for tube packaging or "S" for standard pouch packaging.

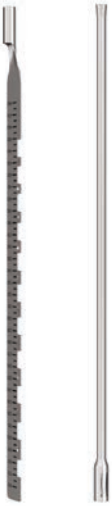
Screw length designations are defined to reflect the readings on the length measurement tools and do not necessarily correspond to the actual total length of the screw.

Alternative Instruments

Alternative Instruments	
03.010.104	03.010.101
	

Alternative Instruments	
03.045.022 for screw lengths up to 120mm	03.010.061 for screw lengths up to 100mm

03.043.001	393.100
	

03.045.035 + 03.045.036	351.717 + 351.719
	

Alternative Instruments	
03.043.014	03.043.016
	

Alternative Instruments	
03.043.015	03.043.016
	

03.045.018	357.399

03.010.000	03.043.030
	

Instruments

03.010.070	Trocar ∅ 4.2 mm, for No. 03.010.065	
03.010.104	Drill Bit ∅ 4.2 mm, calibrated, length 145 mm, 3-flute, for Quick Coupling	
03.010.170	Hammer Guide	
03.019.017	Depth Gauge for Locking Screws, measuring range to 100 mm	
03.010.429	Direct Measuring Device for Drill Bits, length 145 mm	
03.010.500	Handle, with Quick Coupling	
03.010.522	Combined Hammer, 500 g	

03.037.008	Awl ∅ 8 / 4.7 mm, curved, cannulated	
03.043.001	Universal Chuck	
03.043.027	Screwdriver, with T-Handle, with spherical head, hexagonal, 8 mm	
03.045.001	Screwdriver, XL25	
03.045.002	Retention Pin for Screwdriver	
03.045.003	Screwdriver, short, XL25	
03.045.004	Retention Pin for Screwdriver, short	

03.045.018	Guide Wire ∅ 3.2 mm, with Drill Tip, L 400 mm	
03.045.019	Protection Sleeve, ∅ 11/8	
03.045.020	Drill Sleeve, ∅ 4.2 mm	
03.045.022	Drill Bit, calibrated, ∅ 4.2 mm, extra-long	
03.045.035	Direct Measuring Device for Intramedullary Nails	
03.045.036	Tube for Direct Measuring Device	
321.160	Combination Wrench ∅ 11.0 mm	

321.170	Pin Wrench ∅ 4.5 mm, length 120 mm	
03.043.003	Protection Sleeve, short	
03.043.004	Wire Guide, multihole, short	
03.043.016	Drill Bit, flexible, ∅ 12 mm, long	
03.043.028	Driving Cap	
03.043.029	Aiming Arm, radiolucent	
03.043.018	Insertion Handle, radiolucent, short	

03.043.019	Connecting Screw, cannulated, short	
03.043.020	Compression Screw, short	
03.010.101	Drill Bit ∅ 4.2 mm, calibrated, length 145 mm, 3-flute, with Coupling for RDL	
03.010.061	Drill Bit ∅ 4.2 mm, calibrated, length 340 mm, 3-flute, for Quick Coupling, for No. 03.010.065	
393.100	Universal Chuck	
351.717	Depth Gauge for Medullary Nails	
351.719	Elongation Tube for Reaming Rods, for Depth Gauge for Medullary Nails, for Nos. 351.717 and 03.019.001	

03.043.014	Drill Bit, cannulated, ∅ 12 mm, short	
03.043.015	Drill Bit, cannulated, ∅ 12 mm, long	
357.399	Guide Wire ∅ 3.2 mm, with Drill Tip, L 400 mm	

Optional Instruments

03.010.093	Rod Pusher for Reaming Rod with Hexagonal Screwdriver ∅ 8.0 mm	
03.010.495	Intramedullary Reduction Tool, curved, with Quick Coupling, Hex 12 mm	
03.010.496	T-Handle, cannulated, with Quick Coupling, Hex 12 mm	
03.045.005	Screwdriver, with Quick Coupling, hexagonal 12 mm, XL25	
03.045.006	Retention Pin for Screwdriver with Quick Coupling, hexagonal 12 mm	
03.045.007	Screwdriver, with Quick Coupling, hexagonal 12 mm, short, XL25	
03.045.008	Retention Pin for Screwdriver with Quick Coupling, hexagonal 12 mm, short	

03.045.009	Sleeve for Screwdriver	
03.045.010	Sleeve for Screwdriver, short	
03.045.029	Reamer, ∅ 5.5 mm	
03.140.027	Handle, large, cannulated, with Quick Coupling, Hex 12 mm	

MRI INFORMATION

MR SAFETY INFORMATION

Non-clinical testing has demonstrated the DePuy Synthes Tibial Nail Advanced System is MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T transmit quadrature-driven coil only
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m) for 1.5 T or 3.0 T
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg

Under the scan conditions defined above, the DePuy Synthes Tibial Nail Advanced System is expected to produce a maximum temperature rise of 7 °C in 1.5 T and 2 °C in 3.0 T for 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 141 mm from the DePuy Synthes Tibial Nail Advanced System when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

PRECAUTION: It is recommended that the device be kept as far away from the coil wall as possible.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Manufactured by:

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To order (Canada): 800-946-8999

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Note: For recognized manufacturer, refer to the product label.

www.jnjmedicaldevices.com

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