

Set Screw for Trochanteric Fixation Nail. Part of the Titanium Trochanteric Fixation Nail (TFN) System.

Surgical Technique



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.depuyshnthes.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.depuyshnthes.com/hcp/reprocessing-care-maintenance>

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Set Screw for Trochanteric Fixation

Nail. Part of the Titanium Trochanteric Fixation Nail (TFN) System.

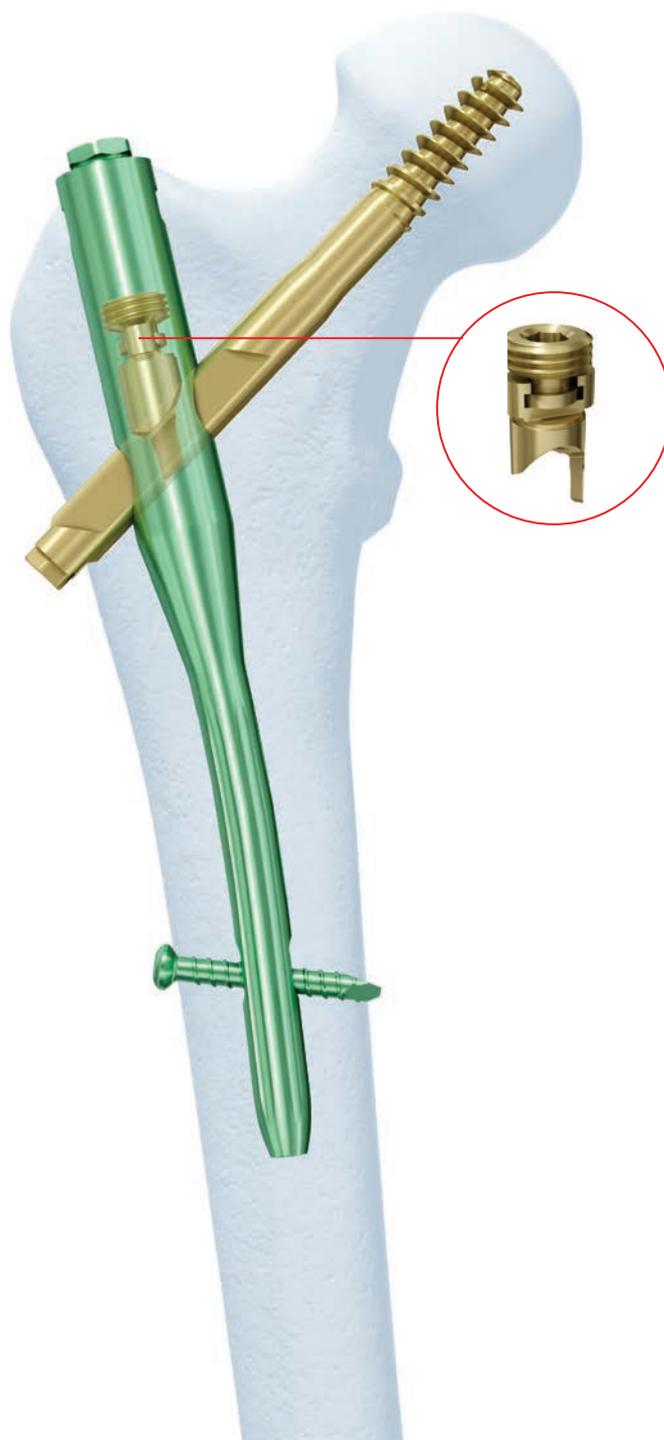
The TFN Set Screw prevents sliding of the TFN blade or screw within the nail.¹ This may be desirable for fixation of some fractures, as determined by the surgeon, fracture pattern, and bone quality.

Note: The TFN Set Screw should only be used for fixation in fractures where sliding is not desired. Additionally, studies have shown that when sliding is prevented in certain fracture patterns, a more rigid construct can be achieved.²

The TFN Set Screw is designed to work with the current Titanium Trochanteric Fixation Nail System. The Set Screw is available in 3 angles (125°, 130° and 135°) and is made of titanium alloy (Ti-6Al-7Nb).

Features

- Set Screw configuration allows for intraoperative choice to either lock or allow sliding of the blade or screw*
- Set Screw is keyed to the nail for assembly
- Instruments and Set Screw for use with existing TFN nails, blades and screws
- Instruments ensure proper tightening torque for a secure construct³



* If sliding is permitted, an end cap must be used.

¹⁺³ Data on file.

² Kuzyk, Paul R. T., Shah, Suraj, Olsen, Michael, et al. "A Biomechanical Comparison of Static Versus Dynamic Lag Screw Modes for Cephalomedullary Nails Used to Fix Unstable Peritrochanteric Fractures." *The Journal of Trauma Injury, Infection and Critical Care*. September 15, 2011.

AO Principles

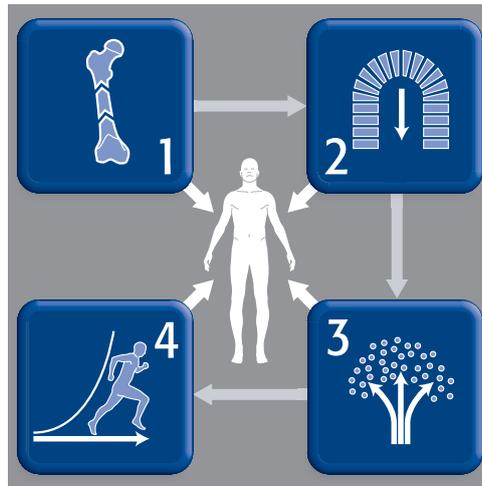
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation^{1,2}.

Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization

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



Stable fixation

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

Preservation of blood supply

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

¹ Müller ME, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg, New York: Springer. 1991.

² Rüedi TP, Buckley RE, Moran CG. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

Indications and Contraindications

Indications

The Synthes Titanium Trochanteric Fixation Nail (TFN) is intended to treat stable and unstable pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof. The Long TFN is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures of osteoporotic bone (including prophylactic use) in both trochanteric and diaphyseal regions, long subtrochanteric fractures, proximal or distal nonunions, malunions, and revisions.

Contraindications

No specific contraindications.



Assembly

Refer to the Titanium Trochanteric Fixation Nail System surgical technique DSEM/TRM/0714/0116 for complete instructions on how to implant and explant the Trochanteric Fixation Nail.

Note: The TFN Set Screw should only be used for fixation in fractures where sliding is not desired.

1 Exchange locking mechanism

Instruments

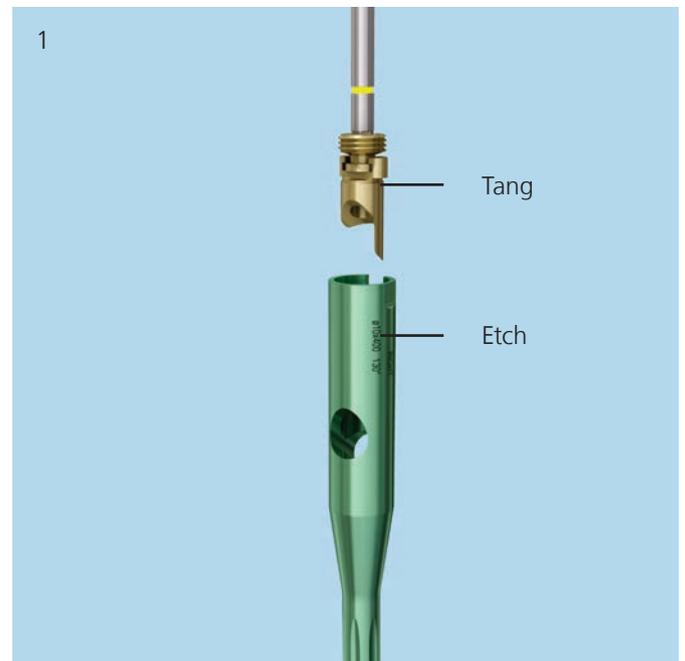
03.010.477	Screwdriver Shaft, hexagonal 5.0 mm, with Hexagonal Coupling 6.0 mm
03.231.013	T-Handle with Torque Limiting Function, 6 Nm

Prior to assembling the insertion handle, exchange the internal locking mechanism with the Set Screw. Using the 5.0 mm hexagonal screwdriver assembly, remove the locking mechanism from the nail.

Select the Set Screw that corresponds with the angle of the nail, for example, 130° Set Screw for a 130° nail.

Note: The Set Screw is keyed so it can only be inserted into the nail in one direction.

Starting with the tang positioned toward the nail's etch (1), insert the Set Screw until the yellow color band sits just below the proximal end of the nail (2).



2

Assemble insertion instruments

Instruments

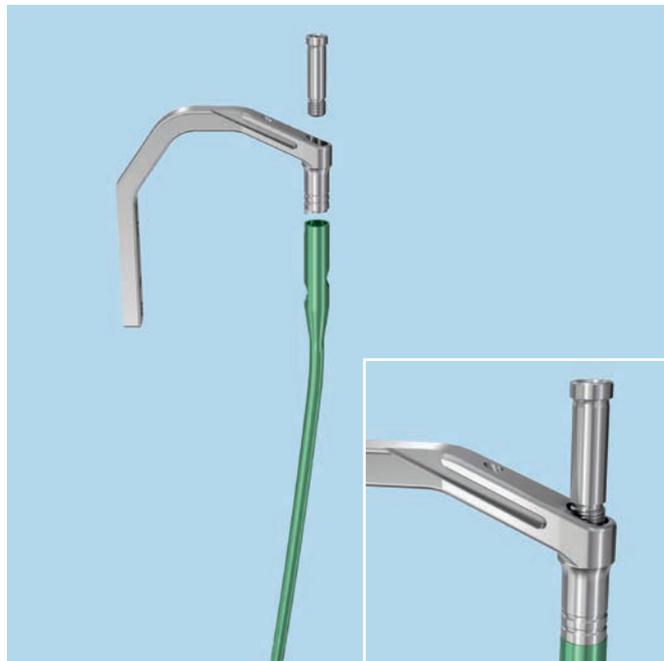
357.397	Connecting Screw, cannulated, for TFN
357.411	Insertion Handle for TFN
357.515	Screwdriver, hexagonal, with spherical head \varnothing 8.0 mm
03.010.477	Screwdriver Shaft, hexagonal 5.0 mm, with Hexagonal Coupling 6.0 mm
03.231.013	T-Handle with Torque Limiting Function, 6 Nm

Optional instruments

03.010.405	Insertion Handle, radiolucent, for PFNA
03.010.474	Connecting Screw, cannulated, for TFN, for No. 03.010.405
357.418	Percutaneous Insertion Handle for TFN
357.419	Percutaneous Connecting Screw, cannulated

Orient the insertion handle laterally and match the geometry of the handle to the nail.

Note: For long nails (300 to 460 mm), the bow of the nail must be aligned with the anterior bow of the femur. Also confirm left or right nail is being assembled for correct affected limb.



Pass the cannulated connecting screw through the insertion handle and into the nail. Secure using the ball hexagonal screwdriver.

Precaution: Ensure that the connecting screw is tight to avoid misalignment when inserting the blade or screw through the aiming arm. Do not attach the aiming arm to the handle until after the nail is fully inserted.



To bring the Set Screw to the appropriate position, pass the 5.0 mm hexagonal screwdriver assembly through the cannulated connecting screw and turn counterclockwise until it stops.

Continue with the procedure until insertion of the head element is complete and good reduction has been achieved.



Proximal Locking

1

Engage locking mechanism

Instruments

03.010.477 Screwdriver Shaft, hexagonal 5.0 mm,
with Hexagonal Coupling 6.0 mm

03.231.013 T-Handle with Torque Limiting Function,
6 Nm

Alternative instrument

03.231.018 Handle with Torque Limiting Function,
6 Nm

If interfragmentary compression or sliding is desired, skip to the optional technique(s) below.

To lock the Set Screw, insert screwdriver assembly and turn clockwise. After one click, the optimal torque is reached.

Precaution: The torque limiting handle ensures that the correct torque is achieved, and therefore sliding is prevented.

- Check position with image intensifier.

Proceed with standard TFN technique, Distal Locking (See TFN surgical technique DSEM/TRM/0714/0116).

Precautions:

- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
 - Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.
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Optional technique: interfragmentary compression

If interfragmentary compression is desired, the Set Screw must be engaged to prevent rotation, but not fully locked. This allows the blade or screw to slide during compression, but prevents rotation.

To allow sliding of the blade or screw, insert the Set Screw to its full depth. Turn the driver counterclockwise a $\frac{1}{4}$ turn.

TFN Blade

Turn the buttress/compression nut (attached to the blade guide sleeve) clockwise by hand or with the assistance of the 4.5 mm pin wrench.

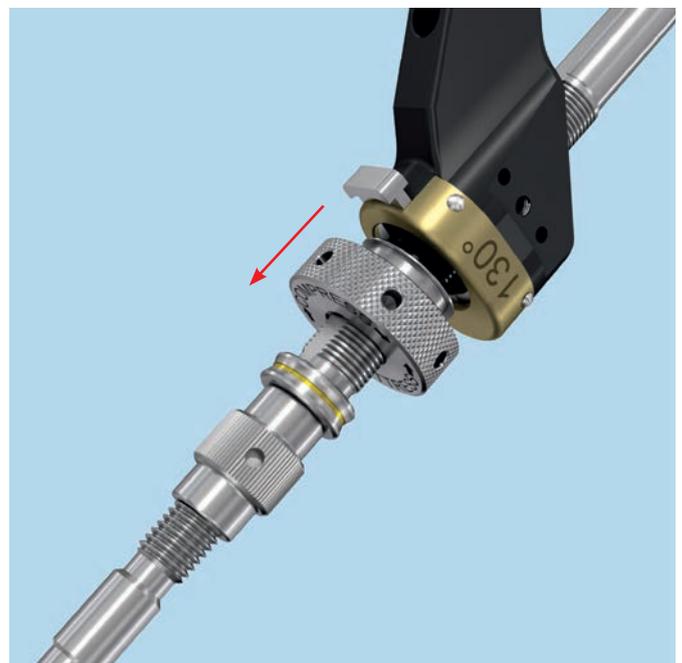
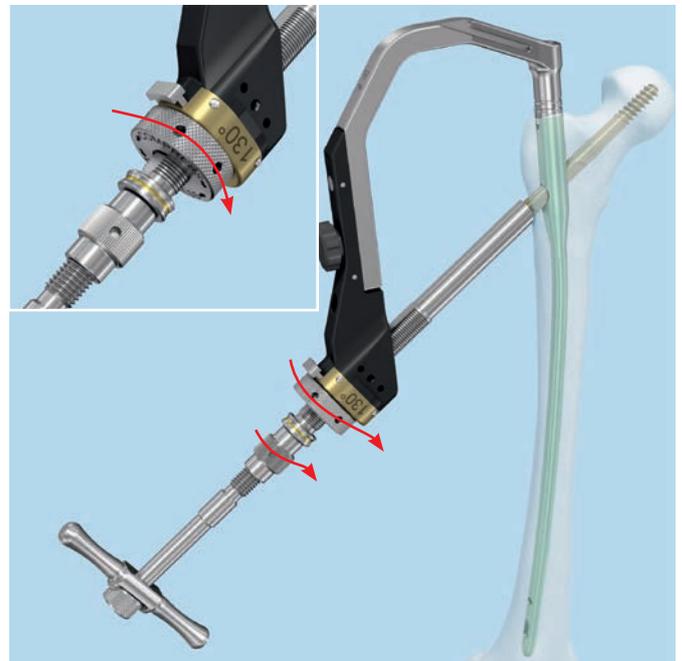
TFN Screw

Advance the compression nut until it abuts the blade guide sleeve. At this point, interfragmentary compression can be obtained by turning either the buttress/compression nut (attached to the blade guide sleeve) or the compression nut (attached to the screw inserter/extractor) clockwise by hand or with the assistance of the 4.5 mm pin wrench.

Once compression has been achieved, the blade or screw can be statically locked. Reinsert the screwdriver assembly and turn clockwise. After one click, the optimal torque is reached.

- Check position with image intensifier.

Remove the connecting screw from the insertion device. If the connecting screw cannot be loosened by hand, use a 5.0 mm hexagonal screwdriver to loosen the connection. Remove the blade guide sleeve from the aiming arm by depressing the button on the aiming arm and pulling out the blade guide sleeve. Proceed with standard TFN technique, Distal Locking (see TFN surgical technique DSEM/TRM/0714/0116).



Optional technique: sliding

Precaution: If sliding is permitted, an end cap **must** be used to prevent the Set Screw from backing out (preventing the blade or screw from rotating, backing out or migrating). Refer to the “Insert End Cap” section of the TFN surgical technique DSEM/TRM/0714/0116).

To allow sliding of the blade or screw, insert the Set Screw to its full depth. Turn the driver counterclockwise a ¼ turn. The blade or screw will be able to slide but the Set Screw will still prevent rotation.

Proceed with standard TFN technique, Distal Locking, and Insert End Cap (see TFN surgical technique DSEM/TRM/0714/0116).

Implant Removal

Note: If the removal of the nail is not possible with the standard instruments, use the special instruments from the Proximal Femoral Nail Removal Set for PFN, TFN and PFNA/PFNA-II (01.010.180) and the corresponding surgical technique (DSEM/TRM/1214/0253).

Implants

Set Screws for Titanium Trochanteric Fixation Nail, sterile

04.032.000S	125°
04.032.001S	130°
04.032.002S	135°



Titanium End Caps for Trochanteric Fixation Nails*

Extension (mm)	
456.311	0
456.312	5
456.313	10



* Available nonsterile or sterile-packed.
Add "S" to the article number to order sterile products.

Instruments

03.010.477 Screwdriver Shaft, hexagonal 5.0 mm,
with Hexagonal Coupling 6.0 mm



03.231.013 T-Handle with Torque Limiting Function,
6 Nm



Alternative instrument

03.231.018 Handle with Torque Limiting Function,
6 Nm



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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