TFN-ADVANCED™

Proximal Femoral Nailing System (TFNA)

Surgical Technique

For Intramedullary Fixation
of Proximal Femoral Fractures

AO approved by AO Technical Commission

DePuy Synthes
THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

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TFN-ADVANCED Proximal Femoral Nailing System (TFNA)

Clinical Cases

Case 1*

- 72-year-old female
- Fracture

AO 31A3 fracture (transverse intertrochanteric fracture pattern) which is unstable and would benefit from a cephalomedullary device. A short or a long nail would be sufficient in this case. A long nail was chosen to “protect” the entire femur from future fracture that could presumably occur at the tip of a short nail.

Case 2*

- 85-year-old
- Fracture

31A3 fracture with subtrochanteric extension (transverse intertrochanteric fracture pattern with comminution and extension down into the subtrocanteric region). This is a highly unstable fracture. The patient had multiple medical problems necessitating a quick procedure be performed closed, if possible, to minimize blood loss and additional stress to the patient’s cardiopulmonary system. The goal was to reduce the fracture as anatomically as possible (and acceptable) without having to open the fracture.

*Case studies are not necessarily predictive of results in other cases. Results in other cases may vary.


Preoperative


Postoperative


Preoperative


Postoperative

The AO Principles of Fracture Management

Mission

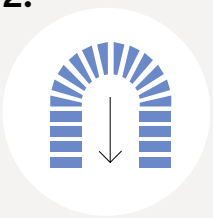
The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

AO Principles[1,2]

1.

Fracture reduction and fixation to restore anatomical relationships.

2.

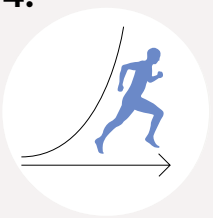


Fracture fixation providing absolute or relative stability, as required by the "personality" of the fracture, the patient, and the injury.

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, Allgöwer M, Schneider R, Willenegger H. Manual of Internal Fixation. 3rd ed. Berlin, Heidelberg New York: Springer 1991.
2. Rüedi TP, RE Buckley, CG Moran. AO Principles of Fracture Management. 2nd ed. Stuttgart, New York: Thieme. 2007.

Indications, Contraindications, and Precautions

Indications

The TFN-ADVANCED Proximal Femoral Nailing System (TFNA) is intended for treatment of fractures in adults and adolescents (12 – 21) in which the growth plates have fused. Specifically, the system is indicated for:

- Stable and unstable pertrochanteric fractures
- Intertrochanteric fractures
- Basal neck fractures
- Combinations of pertrochanteric, intertrochanteric, and basal neck fractures

The Long Nail is additionally intended for treatment of fractures in adults and adolescents (12 – 21) in which the growth plates have fused for the following indications:

- Subtrochanteric fractures
- Pertrochanteric fractures associated with shaft fractures
- Pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions
- Long subtrochanteric fractures
- Proximal or distal nonunions, malunions and revisions

Both the short and long TFNA Systems are additionally indicated for use with cleared, polymethylmethacrylate (PMMA) bone cement that can be delivered through the fenestrated blade or screw via a cannula in skeletally mature adults with risk of cut-out or device instability due to poor bone quality.

Contraindications for TFNA System with PMMA bone cement:

When used with bone cement:

- Risk for intra-articular cement leakage.
- Acute traumatic fractures with good bone quality.
- Intracapsular hip fractures.
- In the presence of active or incompletely treated infection at the site where the bone cement is to be applied.

▲ Precautions:

- 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.
- The TFNA Nail is not intended to be full weight-bearing in patients with complex unstable fractures until sufficient bone consolidation is confirmed in the follow up X-rays.
- Caution should be taken prior to and during implantation in the presence of tumor(s) at the augmentation site.
- 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.

MR information:

The TFN-ADVANCED Proximal Femoral Nailing System has not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

TRAUMACEM V+ Augmentation System

Indications

The TRAUMACEM™ V+ Injectable Bone Cement is indicated for augmentation of the TFN-ADVANCED Proximal Femoral Nailing System through cannulated implants and instruments for patients with poor bone quality (e.g., osteoporosis).

Contraindications

- Risk for cement leakage outside the intended application site
- Intracapsular hip fractures
- PMMA bone cement is contraindicated in the presence of active or incompletely treated infection at the site where the bone cement is to be applied
- Patients with severe cardiac and/or pulmonary insufficiency
- Patients with known hypersensitivity or allergy to any of the components of cement (see Composition of Cement)
- Application to children or to women during pregnancy or lactation
- Arthroplasty procedures
- Acute traumatic fractures with good bone quality

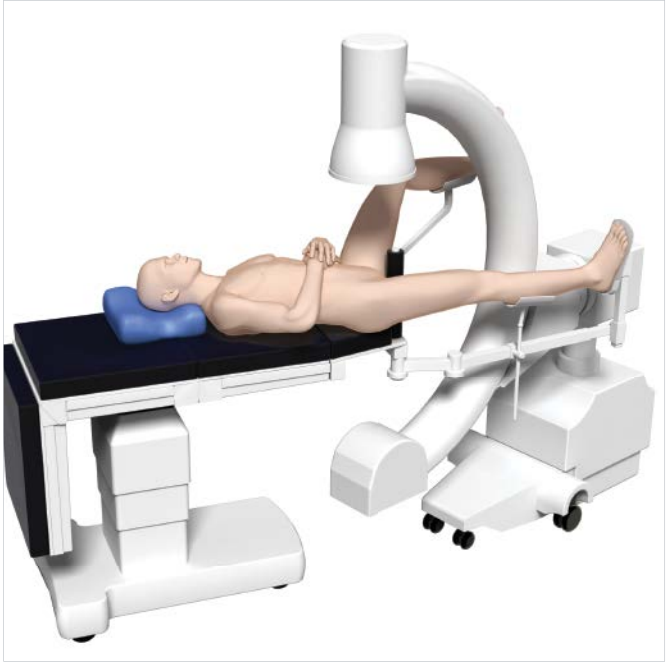
For indications, contraindications, and composition of the "TRAUMACEM V+ Injectable Bone Cement - Sterile," the "TRAUMACEM™ V+ Syringe Kit - Sterile," and the "TRAUMACEM™ V+ Injection Cannula for TFNA - Sterile," please consult the corresponding "Instructions for Use."

Preparation

1. Position patient

- Position the patient in the lateral decubitus or supine position on a fracture or radiolucent table. Position the image intensifier to enable visualization of the proximal femur in both the AP and lateral planes.

  For unimpeded access to the medullary canal, move the upper part of the body approximately 10 – 15° to the contralateral side out of the operative field (or adduct the affected leg by 10 – 15°).



2. Fracture reduction

- Perform closed reduction manually by axial traction under image intensifier control. The use of the large distractor (refer to instructions for use) may be appropriate in certain circumstances.

  If reduction can not be achieved in a closed approach, open reduction may be considered.

3. Determine femoral neck angle

Instruments	
03.037.006	Radiographic Ruler
357.399	3.2 mm Guide Wire 400 mm
Alternative Instruments	
03.045.018*	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm

The three oblique holes at the proximal end of the radiographic ruler are used to determine the femoral neck angle. Select a 3.2 mm guide wire and insert the guide wire in line with one of the grooves marked 125°, 130°, or 135°. Position the ruler over the proximal femur and take an AP image. Select the angle that most closely matches the angle of the femoral neck and position the radiographic ruler such that the guide wire is aimed centrally in the femoral head. Mark the position of the ruler on the skin to assist the next steps. Mark the skin at the proximal outline of the ruler.

Notes:

- The proximal end of the ruler represents the proximal nail end after insertion. The slot on the proximal end refers to the path of the guide wire, used for opening of the femur.
- All AP images of the proximal femur are made with correction for the anteversion, either by internally rotating the femur or by adjustment of the image intensifier.

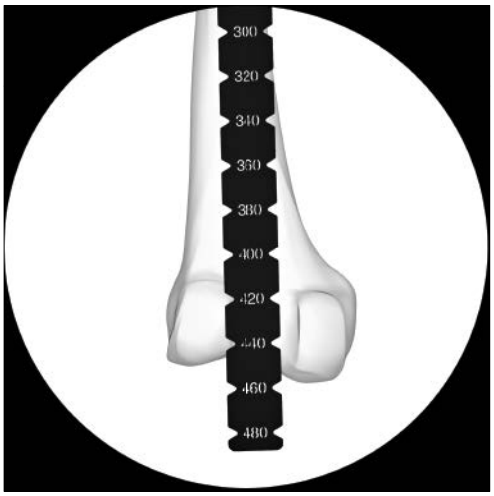
* Available non-sterile or sterile packed. Add "S" to the article number to order sterile products.

4. Determine nail length

Instrument

03.037.006	Radiographic Ruler

Move the image intensifier to the distal femur, place the proximal end of the radiographic ruler at the skin mark, and take an AP image of the distal femur. Verify fracture reduction. Read nail length directly from the ruler image, selecting the measurement that places the distal end of the nail at, or just proximal to, the physeal scar, or the chosen insertion depth.



Alternative:

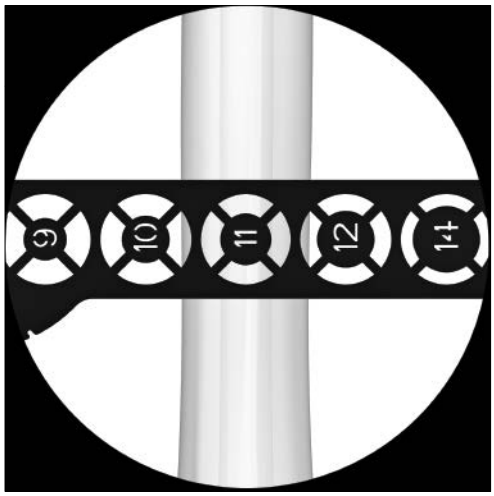
Nail length may also be determined by using a reaming rod, see page 15 for technique.

5. Determine nail diameter

Instrument

03.037.006	Radiographic Ruler

To determine nail diameter, position the image intensifier for an AP view of the femur at the level of the isthmus. Hold the radiographic ruler perpendicular to the femur and position the diameter windows over the isthmus. Read the estimated diameter measurement on the circular indicator that fills the canal.



■ Notes:

The distance of the radiographic ruler from the bone affects the diameter measurement. Estimate the width as follows:

- Distance between the radiographic ruler and bone
  a. 25 mm = 1 mm larger reading
  b. 50 mm = 2 mm larger reading
  c. 100 mm = 3 mm larger reading
- If the reamed technique is used, the diameter of the largest medullary reamer applied must be 0.5 mm to 1.5 mm larger than the nail diameter.

Open Proximal Femur

1. Identify nail entry point

Make a longitudinal incision proximal to the greater trochanter. Carry the dissection down to the gluteus medius fascia longitudinally in the direction of the wound. Separate the underlying muscle fibers and palpate the tip of the greater trochanter.

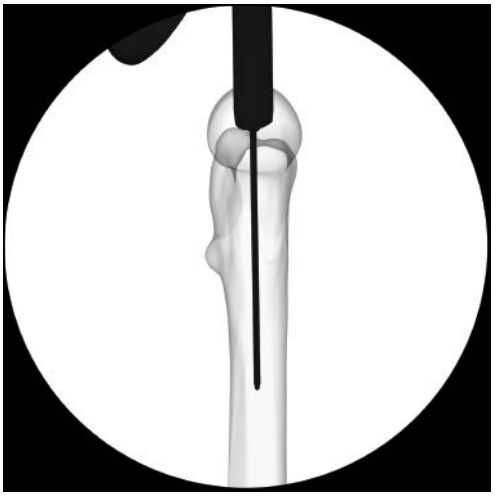
In the AP view, the nail insertion point is on the tip or slightly lateral to the tip of the greater trochanter, in the curved extension of the medullary cavity. This represents a point, 5° lateral of the femoral shaft axis, measured from a point just below the lesser trochanter, as the ML angle of the nail is 5°.

In the lateral view, the entry point for the nail is centered in the greater trochanter and in line with the medullary canal.

2. Insert guide wire

Instruments	
03.037.000	Multi Hole Wire Guide
03.037.001	16 mm Protection Sleeve
357.399	3.2 mm Guide Wire 400 mm
393.10	Universal Chuck with T-Handle
Alternative instruments	
03.045.018*	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm
03.043.001	Universal Chuck
03.037.100	Percutaneous Multi Hole Wire Guide
03.037.101	16 mm Percutaneous Protection Sleeve
09.037.010	3.2 mm Guide Wire 475 mm
393.10	Universal Chuck with T-Handle

Position the 16 mm protection sleeve and the multi hole wire guide assembly at the insertion point.



Insert the guide wire through the wire guide. Confirm guide wire placement in both the AP and lateral planes. Insert to a depth of approximately 15 cm. Remove the wire guide.

Alternatively the guide wire can be inserted without the protection sleeve and multiple wire guide. The protection sleeve and wire guide can then be passed over the guide wire.

If the first guide wire is inserted in an incorrect position, a second guide wire can be inserted through one of the additional holes in the multi hole wire guide at either 4 mm or 6 mm from the central hole. Once the guide wire is in the desired entry point, remove the first guide wire.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Alternative technique

Instrument	
03.037.008	8 mm Cannulated Curved Awl
or	
03.037.007	8 mm Cannulated Straight Awl

Instead of using the guide wire, the 8 mm awl can be used to create a path for the reaming rod. After initial opening with the awl, insert the 950 mm reaming rod through the cannulation.

3. Open canal

Instruments	
03.037.001	16 mm Protection Sleeve
03.037.002	16 mm Cannulated Flexible Drill Bit
or	
03.037.003	16 mm Cannulated Drill Bit

Alternative instruments	
03.037.101	16 mm Percutaneous Protection Sleeve
03.037.102	16 mm Cannulated Percutaneous Flexible Drill Bit
or	
03.037.103	16 mm Cannulated Percutaneous Drill Bit

Guide the 16 mm cannulated drill bit over the guide wire through the 16 mm protection sleeve to the bone and drill to the stop.

Remove and dispose of the guide wire. **Do not reuse.**

3b. Optional technique: Open canal

Optional instruments

03.037.004(S)	16 mm Cannulated Hollow Drill Bit
03.037.104(S)	16 mm Cann Percutaneous Hollow Drill Bit

Ensure the centering mechanism is in the correct position prior to using the hollow drill bit. The centering mechanism should be pushed all the way down toward the cutting end of the hollow drill bit as depicted in the image.

Non-locked position

Correct position for drilling

- Guide the 16 mm cannulated hollow drill bit over the guide wire through the 16 mm protection sleeve to the bone and drill to the stop.

Remove and dispose of the guide wire. **Do not reuse.**

■ Note:

In hard bone after drilling with the hollow drill bit it may be necessary to repeat the opening process with the flexible drill bit.

▲ Precaution:

- **Monitor the drill depth under fluoroscopy throughout the procedure.**

4. Option: Ream medullary canal

If necessary, enlarge the femoral canal to the desired diameter using the medullary reamer and the corresponding technique guide.

Use image intensification to confirm fracture reduction. Insert the reaming rod into the medullary canal to the desired insertion depth. The tip must be correctly positioned in the medullary canal since it determines the final distal position of the nail.

Reaming

Starting with the 8.5 mm diameter reaming head, ream to a diameter of 0.5 mm to 1.5 mm greater than the nail diameter. Ream in 0.5 mm increments and advance the reamer with steady, moderate pressure. Do not force the reamer. Partially retract the reamer repeatedly to clear debris from the medullary canal.

Option: Reamer protection tube

Instruments	
03.037.001	16 mm Protection Sleeve
03.037.005	Reamer Protection Tube
03.037.105	Trocar for Protection Tube

The reamer protection tube can be used to help protect the proximal metaphysis during reaming.

Assemble the reamer protection tube, trocar and protection sleeve together. Then take the reamer protection tube assembly and insert it over the reaming rod, sliding the trocar and reamer protection tube into the bone.

Remove the inner trocar from the assembly and pass the reamer over the reaming rod and through the protection tube. Then ream per the technique described above.

When removing the reamer head through the reamer protection tube be sure to align the angle of the reamer shaft to the protection tube. This will help ensure the reamer head will not get caught on the tube upon removal.

Note:

The reamer protection tube can only be used with reamer heads up to 13.5 mm. Therefore it can only be used for nails up to 12 mm. Use the “Flexible Reamer Set, Long” if reaming down to the distal femur is required.

Option: Determine nail length over reaming rod

Instruments	
03.037.036	Depth Gauge for Trochanteric Nailing System
351.719	Depth Gauge Extension Tube
Alternative Instruments	
03.045.035	Direct measuring device for IM nails
03.045.036	Tube for Direct measuring device

Nail length can be determined over a 950 mm reaming rod. Confirm reaming rod insertion depth under image intensification. Insert the reaming rod to hold fracture reduction. Pass the reaming rod measuring device over the reaming rod and down to the bone. Read nail length directly from the measuring device.

If a 1150 mm reaming rod is used,the nail length measurement should be read off the etched line on the reaming rod.

Insert Nail

1. Assemble insertion instruments

Instruments	
03.037.010	Cannulated Connecting Screw
03.037.012 or 03.037.011 or 03.037.112	Complete Radiolucent Insertion Handle Hybrid Insertion Handle Percutaneous Radiolucent Insertion Handle
03.010.517	T-Handle Ball Hex Screwdriver 8 mm
03.037.028	5 mm Hex Flexible Screwdriver
Alternative Instrument	
03.043.027	Screw driver, hexagonal ∅ 8.0 mm, with T-handle, spherical head, cannulated

Assemble the ball hexagonal screwdriver to the connecting screw by inserting the tip of the screwdriver until it clicks into the recess of the connecting screw.

Match the geometry of the handle to the nail and connect the nail to the insertion handle. The nail will click-in and self-retain.

Pass the connecting screw through the insertion handle and securely tighten with the ball hexagonal screwdriver. Remove the hexagonal screwdriver.

To verify the appropriate position of the locking mechanism for the screw, pass the 5.0 mm flexible screwdriver through the cannulated connecting screw and turn counter clockwise until its stops.

▲ Precautions:

- Ensure that the connection between the nail and the insertion handle is tight (retighten if necessary).
- Do not attach the aiming arm to the handle yet.
- If a 235 mm or longer nail is selected, reconfirm that the correct nail (right or left) is assembled.

2. Insert nail

Instrument	
03.037.012	Complete Radiolucent Insertion Handle
or	
03.037.011	Hybrid Insertion Handle
or	
03.037.112	Percutaneous Radiolucent Insertion Handle

Short nails (170 mm, 200 mm, and 235 mm)

Orient the insertion handle laterally, taking into consideration the anteversion of the femoral head and neck. Manually insert the nail into the femoral opening. When using a reaming rod, pass the cannulated nail over the reaming rod and into the femoral opening.

Under image intensification, verify fracture reduction and insert the nail as far as possible by hand. Use the insertion assembly to manipulate the nail across the fracture. When inserting a short nail (170 mm, 200 mm, and 235 mm), no hammer blows should be required.

Long nails (260 mm to 480 mm)

Orient the insertion handle anteriorly until the nail reaches the isthmus. Manually insert the nail into the femoral opening. When using a reaming rod, pass the cannulated nail over the reaming rod and into the femoral opening. As the nail is advanced, rotate the handle so it is positioned laterally for final seating.

Under image intensification, verify fracture reduction and insert the nail as far as possible by hand. Use the insertion assembly to manipulate the nail across the fracture. Insertion can be aided by light hammer blows on the driving cap, as described in the step below.

If a reaming rod has been used, it should be removed once the nail has crossed the fracture site.

Short nails.

Long nails.

3. Insert nail with hammer (optional)

Instruments	
03.010.522	Spiral Combination Hammer 500 Grams
03.010.523	Driving Cap / Threaded
03.037.031	Combination Wrench 11 mm / Blade Screw
03.037.120	Threaded Hammer Guide Connector
03.010.170	Hammer Guide

To use a hammer, insert the threaded hammer guide connector into the anterior side of the insertion handle. Then screw the driving cap through the insertion handle into the hammer guide connector and tighten with combination wrench. When using the hybrid insertion handle, the threaded hammer guide connector is not used and the driving cap is inserted directly into the hybrid insertion handle.

While applying light blows, monitor the tip of the nail using image intensification. Verify that there is no evidence of impingement distally. Remove the driving cap and hammer guide connector once the nail has been seated.

■ Note:

Using light blows, the hammer can also be used with the threaded hammer guide to back slap the nail if the nail has been slightly over inserted.

▲ Precaution:

Confirm that the nail is tightly connected to the insertion handle, as hammering may loosen the connection.

Proximal Locking

1. Choose aiming arm

Instrument	
03.037.013	130 Deg Aiming Arm
or	
03.037.014*	125 Deg Aiming Arm
or	
03.037.035*	135 Deg Aiming Arm

Ensure that the nail is tightly connected to the insertion handle. Retighten if necessary.

Choose the aiming arm that matches the angle of the nail inserted and securely attach to the insertion handle using the thumb screw.

2. Verify nail insertion depth

Instrument	
357.399	3.2 mm Guide Wire 400 mm

Alternative Instrument	
03.045.018†	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm

Verify nail insertion depth and position for the helical blade / screw. Place a guide wire on the yellow marking of the aiming arm and radiographically check the guide wire position in AP.

*Also available.

† Available non-sterile or sterile packed. Add "S" to the article number to order sterile products.

Alternative technique: Position guide wire with guide wire aiming device

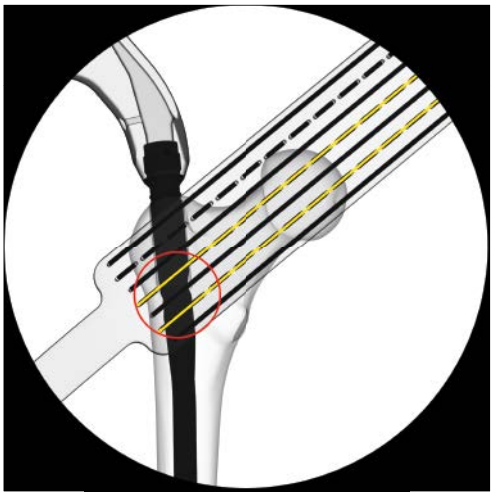
Instruments	
03.010.412	Guide Wire Aiming Device F / TFN For Ant Posterior Orientation
03.010.415	Connecting Screw F / Guide Wire Aiming Device F / TFN
03.010.471*	Guide Wire Aiming Device Offset Block

Attach the guide wire aiming device for AP orientation into the three holes on the anterior side of the aiming arm and lock in place using the connecting screw.

Option:

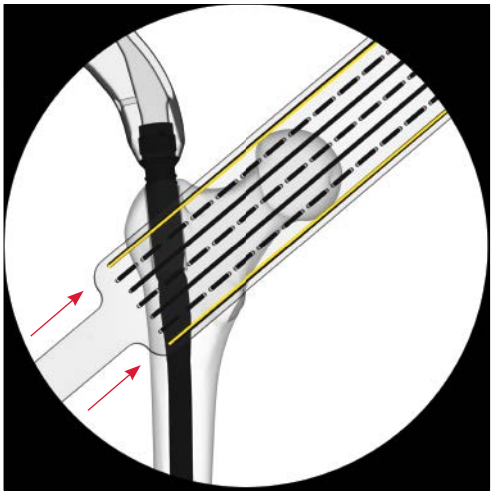
The guide wire aiming device offset block can be added between the aiming arm and the guide wire aiming device to obtain an additional 10 cm of soft tissue clearance.

Position the image intensifier for an AP image. Rotate the image intensifier until any two orientation lines are parallel to the hole for the helical blade / screw. The midline (line between the two orientation lines) represents the guide wire trajectory.



■ Note:

The outer lines can be used to determine the center of the femoral head.

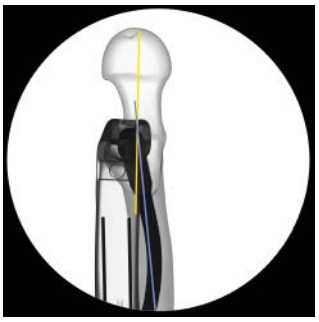


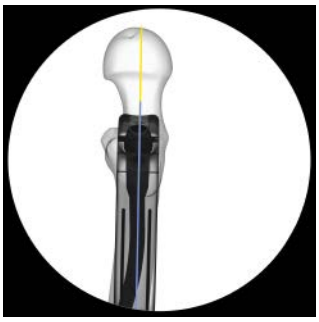
*Also available.

3. Verify nail anteversion

Instrument	
357.399	3.2 mm Guide Wire 400 mm

Alternative Instrument	
03.045.018*	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm





Position the image intensifier in the true lateral view (alignment of the axis of the femoral neck parallel to the axis of the femoral shaft).

Adjust nail rotation until the two radiographic lines on the insertion handle are parallel to the nail.

Option:

A 3.2 mm guide wire can be inserted in the corresponding hole in the insertion handle to predict the location of the guide wire and helical blade/screw.

■ Note:

The guide lines are located in the handle portion of the insertion handle and are made from a radio-opaque material. The lines provide a visual reference for guide wire insertion verifying nail anteversion.

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

4. Insert guide sleeve

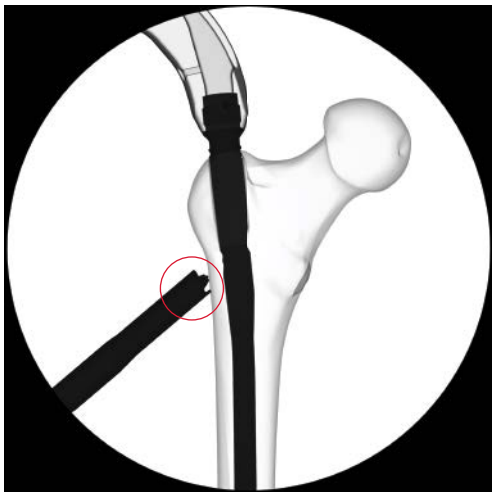
Instruments	
03.037.016	Buttress / Compression Nut
03.037.017	Blade / Screw Guide Sleeve
03.037.018	3.2 mm Wire Guide Sleeve
03.037.019	3.2 mm Trocar
03.010.491	Long Scalpel Handle

To make an incision to accommodate the path of the sleeve assembly, insert the scalpel handle with scalpel blade attached through the corresponding hole of the aiming arm. Ensure that the incision and dissection of the fascia is in line with the path of the guide sleeve.

Thread the buttress / compression nut onto the blade / screw guide sleeve, to the black marking on the blade / screw guide sleeve.

Insert the wire guide sleeve and trocar into the blade / screw guide sleeve. Place the yellow marked guide sleeve assembly through the aiming arm and through the soft tissue to the bone. Slightly rotating the wire guide sleeve while pushing the guide sleeve assembly through the soft tissue may help facilitate insertion. The buttress / compression nut will snap into the aiming arm.

- Turn the buttress/compression nut counterclockwise to advance the guide sleeve to the bone. Take an AP image to confirm that the tooth on the guide sleeve is just touching the lateral cortex.



▲ Precautions:

- **The distal tooth of the guide sleeve should rest on the lateral cortex. Do not over tighten on the cortex as this may affect the accuracy of the aiming assembly.**
- **The fatigue strength of the nail may be affected and may contribute to the potential for the nail to fracture if the nail is damaged during any step of the helical blade/screw reaming, in addition to other factors such as fracture reduction, surgical technique, obesity, level of activity/weight-bearing, non-union, or delayed union.**

Using a light hammer blow, hit the trocar into the bone to create an indentation in the bone which will help prevent the guide wire from skiving off of the bone in the next step.

- Reconfirm fracture reduction using image intensification.

5. Insert guide wire for blade or screw

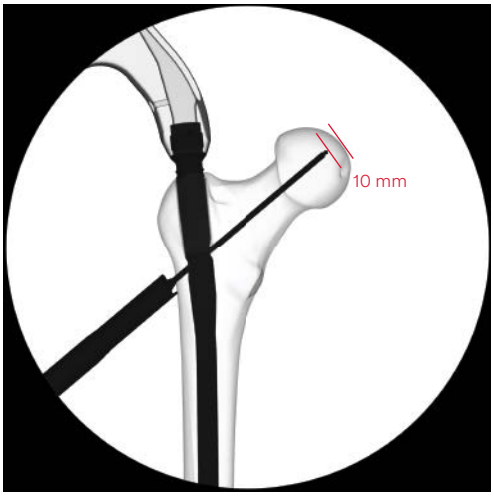
Instruments	
03.037.019	3.2 mm Trocar
357.399	3.2 mm Guide Wire 400 mm
Alternative Instrument	
03.045.018*	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm

■ Note:

Instrument 09.037.010 (3.2 mm Guide Wire 475 mm) should not be used for head element placement. This instrument is etched with two bands to aid in identification and is intended only for nail entry point.

Remove the 3.2 mm trocar and pass a new 3.2 mm guide wire through the wire guide to the bone. Advance the guide wire, under power, into the femoral head, stopping approximately 10 mm below the joint level.

The guide wire should be centered in the femoral head and neck in both the AP and lateral planes. The tip of the guide wire is positioned where the tip of the head element will be when the head element is properly inserted.



Confirm guide wire placement, in both planes, using the image intensifier.

▲ Precautions:

- **If the nail must be repositioned to improve guide wire placement, remove the sleeve assembly and adjust with the insertion handle. Make a new incision for insertion of the guide sleeve. Do not pull on the guide sleeve or power tool to make this adjustment as this could affect the accuracy of the aiming.**
- **The fatigue strength of the nail may be affected and may contribute to the potential for the nail to fracture if the nail is damaged during any step of the helical blade/screw reaming, in addition to other factors such as fracture reduction, surgical technique, obesity, level of activity/weight-bearing, non-union, or delayed union.**
- **Do not reuse guide wires as they may bend during initial use. If the guide wire is deformed during insertion use a new guide wire and discard deformed guide wire.**

■ Note:

When inserting the guide wire in patients with larger anatomies, you may need to stop during insertion of the wire and remove the wire guide sleeve and continue advancing the wire to the desired depth. This is most likely to occur in anatomies requiring blade/screw lengths of 120 mm or larger.

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

Optional technique: Rotational control of femoral head

Instruments	
357.399	3.2 mm Guide Wire 400 mm
357.413	5.6 mm / 3.2 mm Drill Guide 198 mm

Alternative Instrument	
03.045.018*	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm

If the fracture line is perpendicular to the axis of the head element or if rotational control of the femoral head during head element insertion is a concern, the following technique may be utilized.

Pass the 5.6 mm / 3.2 mm drill guide through the corresponding anterior or posterior hole on the aiming arm. Make a stab incision and pass the guide to the bone. Advance a 3.2 mm guide wire into the femoral head. Monitor passage with the image intensifier.

Repeat to place a second guide wire if necessary.

The guide wires will converge toward the tip of the head element, in the lateral view, but will not touch it. The guide wires should be used for provisional fixation only and removed once the head element has been inserted.

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

6. Measure for length of blade or screw

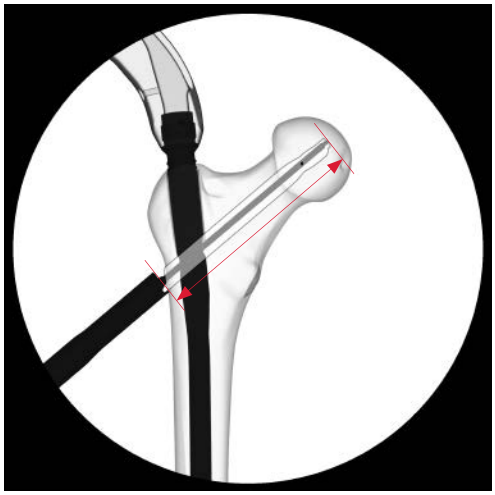
Instrument

03.037.020	Helical Blade / Screw Measuring Device

To measure for blade or screw length, pass the helical blade / screw measuring device over the guide wire to the back of the guide sleeve. Blade or screw length is read directly from the measuring device. No calculations are required.

■ Note:

The measurement is calibrated from the tip of the guide wire to the tip of the tooth on the guide sleeve.



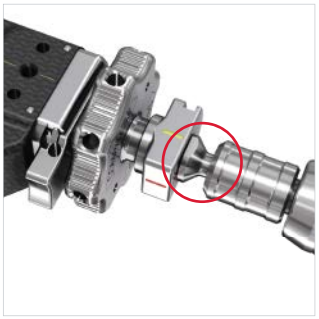
7. Drill for helical blade or screw

Instruments	
03.037.017	Blade / Screw Guide Sleeve
03.037.021	10 mm Cannulated Tapered Drill Bit

Remove the wire guide sleeve from the blade / screw guide sleeve. Place the 10 mm cannulated tapered drill bit in a power tool. Pass the drill bit over the guide wire, through the blade / screw guide sleeve, and advance under power. Drill to the stop. This will open the lateral cortex.

■ Note:

If the guide wire deflected as it passed into the femoral head / neck, it may be removed before drilling and blade / screw insertion. If the guide wire falls out or comes out when the drill bit is removed, it may be left out for blade / screw insertion. Care should be taken to ensure the orientation of the insertion handle and aiming arm is not altered.



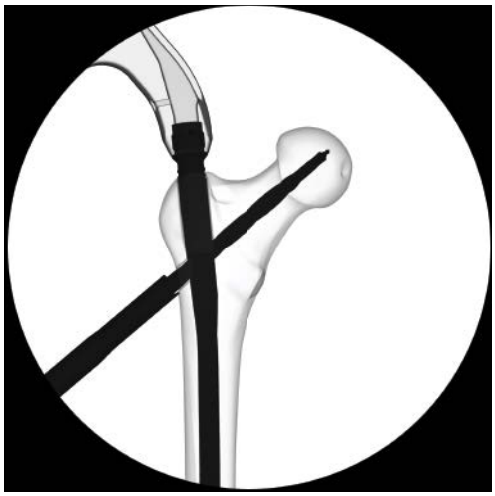
Option: Drilling for dense bone or when using a TFNA Screw

Instruments	
03.037.022	6 mm / 9 mm Cannulated Stepped Drill Bit
03.037.023	Drill Stop for 03.037.022
03.010.093	Reaming Rod Push Rod with Ball Handle

For dense bone or when using a TFNA Screw, the 6 mm / 9 mm cannulated stepped drill bit should be used to prepare a path for the full length of the shaft of the head element. The stepped drill bit should be used only after the cortex has been opened using the 10 mm tapered drill bit.

Pass the drill stop over the back end of the stepped drill bit and check the drill stop for wear per the instructions on page 50. Adjust the setting to the measured blade or screw length. Pass the drill bit over the guide wire, through the guide sleeve and advance under power. Drill to the stop.

Use the rod pusher through the power tool to hold the guide wire in place while removing the 6 mm / 9 mm cannulated stepped drill.



■ Note:

- Clean the flutes if high resistance is felt.
- Drill always stops 5 mm short of the wire tip.
- Rod pusher can be used to hold the guide wire in the bone when the drill is retracted.

▲ Precaution:

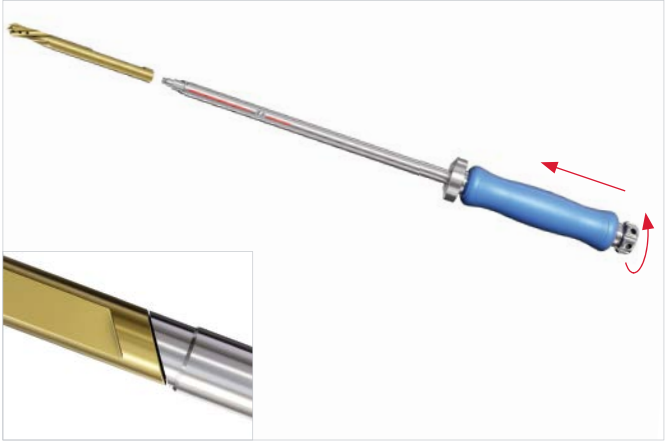
Monitor the drill depth under fluoroscopy throughout the procedure.

Option A: Blade Insertion

8a. Assemble helical blade

Instruments	
03.037.024	Helical Blade Inserter
03.037.026	Helical Blade / Screw Coupling Screw

Insert the cannulated helical blade coupling screw and thread in until fully captured in the helical blade inserter. The coupling screw will remain attached to the inserter. Select the appropriate length helical blade as measured. Align the back end of the helical blade with the inserter. Further thread the coupling screw into the helical blade and finger tighten the assembly.



9a. Insert helical blade

Instrument	
03.010.522	Spiral Combination Hammer 500 Grams

Pass the helical blade insertion assembly through the helical blade / screw guide sleeve and align the red line on the inserter shaft with the red line on the guide sleeve. Advance the blade as far as possible by hand. Use light hammer blows on the back of the coupling screw until the blade inserter comes to a stop at the back of the blade / screw guide sleeve. In the final position the yellow line of the helical blade / screw guide sleeve and the helical blade inserter are in alignment.

The helical blade **MUST** be fully inserted.

▲ Precautions:

- Image intensifier should be used during blade insertion to monitor positioning.
- Assure that the guide wire is in place while inserting the helical blade to prevent the cannulation from clogging, impeding an optional augmentation procedure.

Option: Intraoperative exchange of the blade

Instrument	
03.010.523	Driving Cap / Threaded

To intraoperatively exchange the blade, attach the driving cap / threaded to the back of the coupling screw. Use the hammer to back slap if needed.

Option B: Screw insertion

8b. Tap for screw (optional)

Instrument

03.037.027	Tap for Screw

The tap may be used to prepare a pathway for the screw.

■ Note:

Only use the tap in dense bone.

Pass the tap over the guide wire, through the guide sleeve and through the nail. Advance the tap manually by turning clockwise until the measurement graduations on the shaft of the tap reach the measurement selected for the screw.

▲ Precautions:

There is no stop on the tap so monitoring insertion via the following methods is recommended:

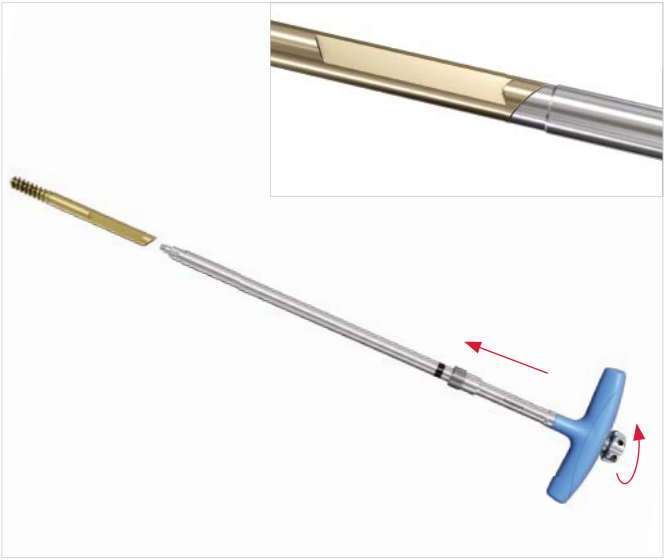
- **Monitor the depth under fluoroscopy.**
- **Monitor the respective graduations of the instrument shaft in relation to the guide sleeve.**

Remove the tap by turning counterclockwise.

9b. Assemble screw

Instruments

03.037.025	Screw Inserter
03.037.026	Helical Blade / Screw Coupling Screw



Insert the cannulated coupling screw and thread in until fully captured in the screw inserter. The coupling screw will remain attached to the inserter. Select the appropriate length screw as measured. Align the back end of the screw with the inserter. Further thread the coupling screw into the screw and finger tighten the assembly.

10b. Insert screw

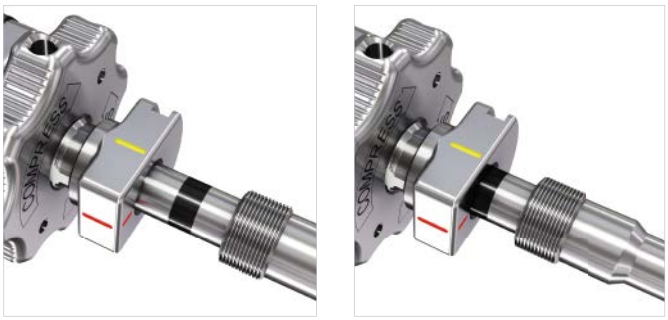
Starting notes:

- The screw advances in 1.75 mm increments by turning the handle 180° (or 3.5 mm by turning 360°).
- When adjusting for final positioning, always rotate the handle clockwise, further engaging the screw in the bone. Do not rotate counterclockwise, as this will leave a gap between the screw and the bone.
- The screw can be over inserted a maximum of 1 (one) full turn.
- The etched image of the screw on the inserter shaft indicates the orientation of the lateral oblique cut of the screw.

Pass the screw insertion assembly over the guide wire, through the guide sleeve and through the nail. Advance the screw by turning the inserter clockwise until the line on the inserter meets the flange surface of the guide sleeve. At this depth the screw tip will be positioned at the tip of the guide wire. Assure that the inserter handle is aligned to the aiming arm. This is essential for proper engagement of the locking mechanism.

▲ Precautions:

- Image intensifier should be used during screw insertion to monitor positioning.
- Assure that the guide wire is in place while inserting the screw to prevent the cannulation from clogging, impeding an optional augmentation procedure.



11. Rotational locking

Engaging locking mechanism against rotation

Instrument	
03.037.028	5 mm Hex Flexible Screwdriver

The preassembled locking mechanism in the nail must be advanced to control the rotation of the blade or screw. Pass the 5 mm flexible screwdriver through the cannulated connecting screw and insertion handle until it is seated in the hexagonal recess of the locking mechanism. Turn clockwise to advance the locking mechanism. Advance the screwdriver down until it stops completely, then back the screwdriver off by turning counterclockwise 1/2 turn (180 degrees). The blade or screw is now locked in rotation but can still slide.

▲ Precaution:

If the locking mechanism is not turned back 1/2 turn after initial tightening as described above, controlled collapse and compression of the fracture may not occur.

*Also available.

Option: Interfragmentary Compression

Option A: Blade compression

Instrument	
321.17	4.5 mm Pin Wrench 120 mm

Once the blade has been locked in rotation, interfragmentary compression can be obtained by turning the buttress / compression nut clockwise by hand. For additional leverage, use the 4.5 mm pin wrench.

▲ Precaution:

Caution should be taken when using the buttress / compression nut with the pin wrench to avoid over compression which could potentially cause the blade or screw to lose purchase in the bone, especially inpatients with poor bone quality.

Option B: Screw compression

Instruments	
03.037.116	Compression Nut for Screw Inserter
321.17	4.5 mm Pin Wrench 120 mm

Once the screw has been locked in rotation, interfragmentary compression can be obtained by mounting the compression nut onto the screw inserter, advancing it until it abuts the guide sleeve, and then turning the buttress / compression nut clockwise by hand or with the assistance of the 4.5 mm pin wrench.

▲ Precaution:

Caution should be taken when using the buttress / compression nut with the pin wrench to avoid over compression which could potentially cause the blade or screw to lose purchase in the bone, especially in patients with poor bone quality.

Option: Static locking

Engage locking mechanism to restrict sliding

Instruments	
03.037.029	5 mm Hex Screwdriver Shaft*
03.140.023	Torque Limiting Attachment 6 Nm**
03.010.496	T-Handle / Cannulated with Quick Coupling
Alternative instrument	
03.231.018	6 Nm Torque Limiting Blue Handle with 6 mm Hex Coupling

Once compression has been achieved, the blade or screw can be statically locked to restrict sliding of the blade/screw through the nail.

■ Note:

The blade or screw may slide after load is placed on the construct. The design of the components enabling static locking are based on a friction fit, where the user tightens the locking mechanism down onto the surface of the blade/screw. In some instances, sliding may occur.

Assemble the 6 Nm torque limiting attachment into the T-Handle and then the 5 mm hex shaft into the torque limiting attachment to complete the static locking screwdriver assembly.

Pass the static locking screwdriver assembly through the cannulated connecting screw and insertion handle until it is seated in the hexagonal recess of the lock drive and turn clockwise to advance. After one click, the optimal torque is reached and the blade or screw is statically locked.

■ Note:

The torque limiting attachment ensures that the correct torque is achieved, thus ensuring sliding is restricted.

*Also available.

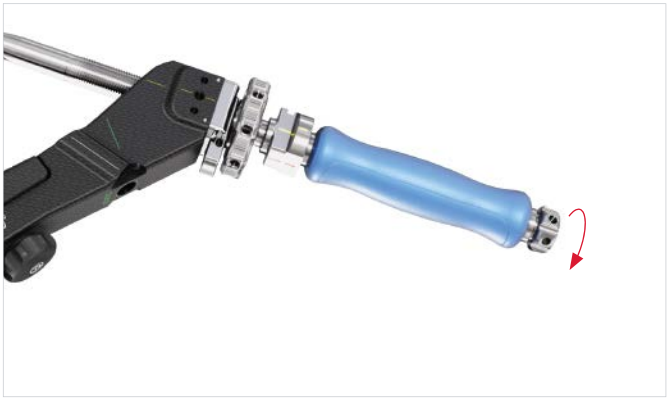
**Recalibration of the torque limiter:
DePuy Synthes Trauma recommends annual servicing and inspection by the original manufacturer. The torque limiter has to be sent to your DePuy Synthes Trauma repair center annually for calibration. The user accepts the responsibility for this annual calibration.

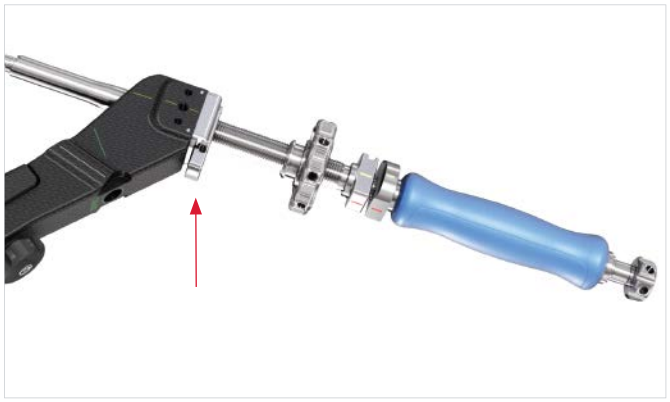
12. Remove proximal locking instruments

Disconnect the coupling screw from the blade or screw and remove the inserter/coupling screw assembly. If the connecting screw cannot be loosened by hand, use the 5 mm flexible hexagonal screwdriver to loosen the connection.

If no augmentation is planned, remove the guide sleeve from the aiming arm by depressing the locking device on the aiming arm and pulling out the guide sleeve. Remove the guide wire. Continue with distal locking.

If augmentation is planned, remove the helical blade impactor/screw inserter and leave the guide sleeve in place to facilitate augmentation.





Augmentation

General notes

- It is recommended to use 3 mL of cement for augmentation. This amount of cement minimizes the risk of avascular necrosis and is sufficient to achieve the desired stability. The injected amount must not exceed 6 mL of cement.
- Aimed placement of cement is around the helical part of the blade/screw. The exact amount of cement depends on surgeon discretion informed by patient anatomy. It is recommended to control injection under fluoroscopy in order to maintain a minimum distance of 6 mm between the bone cement and the joint surface. Filling of the cavity lateral to the helical part of the blade/screw is not necessary.
- The fenestrated blade and fenestrated screw may be used with or without polymethylmethacrylate (PMMA) cement. The non-fenestrated blade and non-fenestrated screw may only be used without polymethylmethacrylate (PMMA) cement.

Product Code: 07.702.040S
Description: TRAUMACEM V+ Injectable Bone Cement, sterile

TRAUMACEM V+ Injectable Bone Cement is a cleared PMMA bone cement with the required parameters to be utilized in this application.

The working time for TRAUMACEM V+ Injectable Bone Cement at room temperature (20° C) is approximately 27 minutes. At body temperature (37° C) the setting time is 15 minutes. Mobilizing/repositioning the patient before 15 minutes after the last injection should therefore be avoided.

Important Information for Physician

The physician should, by specific training and experience, be thoroughly familiar with the properties, handling characteristics, and application of bone cements. Because the handling and curing characteristics of this bone cement vary with temperature, humidity, and mixing technique, they are best determined by the surgeon's actual experience. For this reason, the physician is strongly recommended to carry out a trial run of the entire mixing, handling, and setting process prior to performing a surgical procedure with TRAUMACEM V+ Injectable Bone Cement.

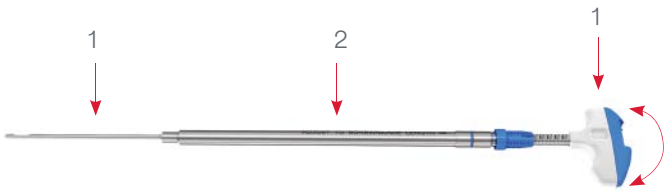
■ Note:

Refer to bone cement instructions for use.

1. Adjust sleeve of side-opening cannula

Instrument	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

Adjust the sleeve of the side-opening cannula to the selected head element length. Length adjustments are made by turning the sleeve (2), while holding the handle of the side-opening cannula (1). One clockwise turn of the sleeve relates to 5 mm lateral axial movement of the side-opening cannula.



2. Check for possible cement leakage into joint

Instrument	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

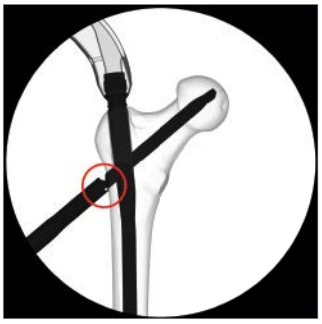
Other materials
1–2 Syringes with Luer lock
Radiographic contrast agent
Saline solution

Attach the syringe with luer lock to the side-opening cannula and prefill the side-opening cannula with radiographic contrast agent.

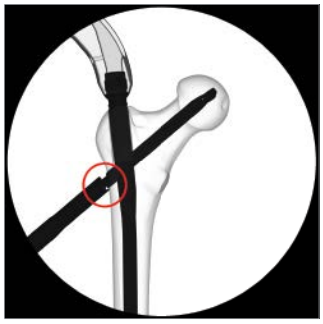
Insert the side-opening cannula through the guide sleeve into the helical blade/screw until the stop.

Confirm that the selected length on the side-opening cannula corresponds with the length of the helical blade/screw and verify under image intensification that the side opening cannula is fully inserted.

At the correct position the tip of the sleeve has disappeared in the lateral end of the helical blade/screw. Monitor the correct position of the sleeve throughout the procedure.



Wrong–tip of the sleeve visible.



Correct–tip has disappeared in the screw/blade.

Inject radiographic contrast agent into the femoral head and monitor the flow under image intensification.

Remove the side-opening cannula.

Wash the radiographic contrast agent out of the cannula using a saline solution and another syringe, attached to the side-opening cannula.

▲ Warning:

Do not augment if radiographic contrast agent leaks into the joint and proceed with distal locking. Radiographic contrast agent leakage into the joint indicates significant risk for intra-articular PMMA bone cement leakage and therefore augmentation is contraindicated.

▲ Precautions:

- **Do not use radiographic contrast agents that are contraindicated for this application.**
- **Consult the manufacturer's directions on indications, contraindications, use, precautions, warnings and side effects of the radiographic contrast agent.**

No leakage into joint.

Leakage into joint, do not augment.

3. Prepare cement

Instrument	
07.702.040S	TRAUMACEM V+ Injectable Bone Cement, sterile

Hold the TRAUMACEM V+ Injectable Bone Cement upright and gently slap with the finger tip at the top of the mixing device in order to ensure no cement powder sticks to the cartridge and sterilization lid.

Pull the handle until it is fully retracted.

■ Note:

Make sure to always handle the mixing device by gripping the blue part located directly below the transparent cartridge. If the transparent part is used as gripping surface, the excess body heat provided by the user's hand might result in a shorter working time than intended.

Open the glass ampoule by breaking the bottle neck with the plastic cap (1). Remove and dispose the mixing device sterilization lid. Pour all monomer from the glass ampoule into the cement powder (2) and close the mixing device tightly using the enclosed transferring lid.

■ Note:

Always use the full amounts of monomer liquid and polymer powder provided in the kit, respectively, when mixing TRAUMACEM V+ Injectable Bone Cement. Otherwise, the behavior of the TRAUMACEM V+ Injectable Bone Cement can no longer be guaranteed. Using only one of the components is not permitted.

Mix the TRAUMACEM V+ Injectable Bone Cement by moving the blue handle back and forth from stop to stop approximately 20 times (1). Perform the first mixing strokes slowly with oscillating-rotating movements (2). After mixing fully retract the handle (3).

■ Note:

Ensure thorough mixing.

4. Fill injection syringes

Instrument	
03.702.150S	TRAUMACEM V+ Syringe Kit, 4 x 1 mL, 2 x 2 mL, sterile

Once the cement has been mixed using the TRAUMACEM V+ Injectable Bone Cement remove the small, transparent mixer lid (1). Connect the stop-cock (the side without the funnel) to the mixer. Ensure a tight fit between the mixer and the stop-cock (2).

■ Note:

The application of excessive torque will break the stop-cock.

First remove the air from the system. With the valve open, gently turn the handle of the cement mixer clockwise. The mixer piston will advance in the translucent cartridge and a steady flow of cement will move into the stop-cock. As soon as the cement is visible in the stopcock, close the valve (3).

■ Note:

Do not push to transfer cement.

Attach a 2 mL (white) syringe to the one way stop-cock (funnel side).

Open the one way stop-cock (the “off” sign facing away from the syringe).

Gently turn the handle of the cement mixer clockwise to advance the piston. As soon as the syringe is filled, close the stop-cock again, by turning the “off” sign towards the mixer.

Disconnect the full syringe and attach the next syringe to be filled. Avoid spillage of cement into the funnel during the transfer process and remove excess cement to avoid accidental pollution of the protection sleeve, blade or screw. Continue to fill all the 1 mL (blue) and 2 mL (white) syringes in the same manner. Always fill all syringes.

5. Prefill the side-opening cannula with cement

Instrument	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

Attach a cement filled 2 mL syringe to the side-opening cannula. Prefill the side-opening cannula with the 2 mL of cement from the syringe. Attach another filled 2 mL syringe and fill the side-opening cannula until the cement is coming out of the side opening, representing 4 mL of cement filled into the cannula. Remove and discard the syringes. Attach a filled 1 mL syringe to the side-opening cannula in preparation of the augmentation.

In case of cement leakage from the side opening, remove the excess cement in order to avoid accidental pollution of the protection sleeve or blade/screw.

■ Note:

1 mL syringes must be used to inject cement. The 2 mL syringes are not suited to augment the blade/screw. Upon injection of 3 1 mL syringes, approximately 3 mL of cement has been delivered out of the head element.

6. Insert side-opening cannula

Confirm that the selected length on the side-opening cannula corresponds with the length of the helical blade/screw.

Insert the side-opening cannula through the guide sleeve into the blade/screw until the stop.

- Verify under image intensification that the side-opening cannula is fully inserted.

7. Augmentation with cement

Instrument

03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile

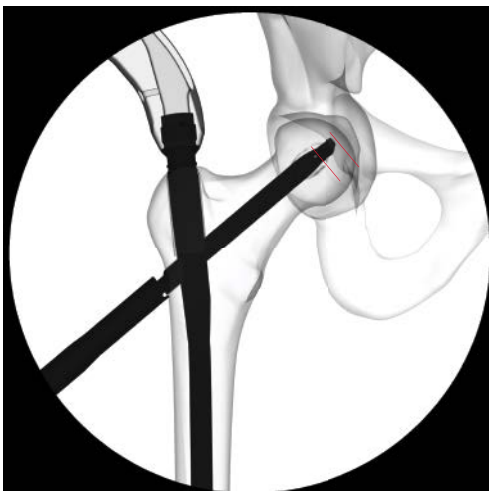
Injection of cement into the femoral head is performed using 1 mL syringes.

Slowly inject the cement using 1 mL syringes. Optimize the filling by rotating the handle to inject cement around the blade/screw. It is recommended that the surgeon maintain a minimum distance of 6 mm between the boundary of the cement and the joint surface. If noted under fluoroscopy that the cement is traveling towards the joint surface, move the cannula laterally by rotating the sleeve 1 clockwise turn.

▲ Warning:

The 6-mm minimum distance is recommended to reduce the risk of thermal injury to the adjacent cartilage tissue.

Visualization of cement during injection must be guaranteed. Continuously monitor the cement flow under image intensification.



Correct distance between cement boundary and the joint surface.

▲ Precautions:

- **Do not advance the cannula more than 5 mm over the selected head element length. This would result in injection of cement in front of the head element tip where no additional stability is achieved and the risk of penetration and cement leakage is increased.**
- **In the event that there is danger of cement leakage into the joint or fracture gap, stop injection immediately.**

■ Note:

The arrow on the handle indicates the position of the side-opening window of the cannula.

Options:

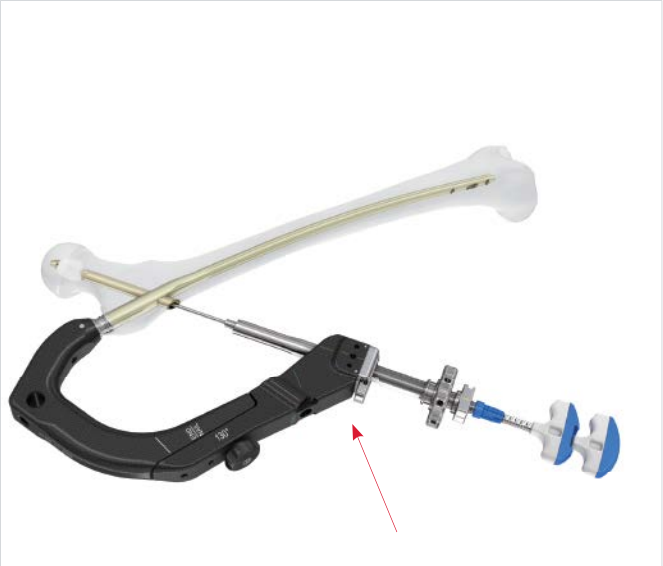
- Injection of cement can be continued using the plunger when the viscosity is increasing or the cement in the cavity of the side-opening cannula is necessary for augmentation. Approximately 3 mL of cement contained in the side-opening cannula can be injected with the plunger.
- Remove the 1 mL syringe and insert the plunger. Continue the injection using the plunger and optimize the filling by rotating the handle.

▲ Warnings:

- If the extravasated cement conforms to the architecture of the hip joint it may not need to be removed, however if it does not conform and is abrasive or damages the articular surface then removal of the extruded cement is at the discretion of the surgeon.
- To remove the cement, the treating physician has the option of either hip arthroscopy, arthroplasty, or open arthrotomy to remove the extruded pieces. The timing of the removal is at the discretion of the physician after appropriate evaluation of the patient.

8. Remove the side-opening cannula

Push the locking device on the aiming arm to remove the side-opening cannula/guide sleeve assembly. Remove the side-opening cannula as soon as the injection is complete.



Distal Locking – Short Nails (170 mm, 200 mm, and 235 mm)

1. Reconfirm reduction

Instrument	
03.010.491	Long Scalpel Handle

Confirm reduction of the fracture with AP and lateral images.

Make a stab incision by sliding the scalpel through the hole of the aiming arm.

2. Drill and measure for locking screw

Instruments	
03.025.040	11.0 mm / 8.0 mm Protection Sleeve 188 mm for ASLS
03.010.065	8.0 mm / 4.2 mm Drill Sleeve 200 mm
03.010.070	4.2 mm Trocar 210 mm
03.010.061	4.2 mm Three-Fluted Drill Bit QC / 330 mm / 100 mm Calibration
Alternative Instruments	
03.045.022*	Drill Bit Ø 4.2 mm, calibrated, 120 mm
03.045.019	Protection Sleeve, Ø 11/8
03.045.020	Drill Sleeve, Ø 4.2 mm

Insert the green triple trocar assembly through the aiming arm to the bone.

■ Note:

Using a light hammer blow, hit the trocar into the bone to create an indentation in the bone which will help prevent the drill bit from skiving off of the bone.

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

Remove the trocar and drill through both cortices using the calibrated 4.2 mm three-fluted drill bit.

Read the length for the locking screw directly from the drill bit at the back of the drill sleeve. Press the drill sleeve to the bone to ensure accurate measurement.

Alternative technique

Instrument	
03.010.428	Depth Gauge for Locking Screws to 100 mm for IM Nails
or	
03.010.072	Depth Gauge for Locking Screws to 100 mm for IM Nails
Alternative Instrument	
03.019.017	Depth Gauge for Locking Screws, measuring range up to 100 mm

The depth gauge for locking screws may be used through the 11.0 mm/8.0 mm protection sleeve to determine locking screw length. Remove the 8.0 mm/4.2 mm drill sleeve and pass the measuring hook through the 11.0 mm/8.0 mm protection sleeve. Read locking screw length directly from the measuring device at the back of the protection sleeve.

3. Insert locking screw

Instruments	
03.010.518	STARDRIVE™ Screwdriver / T25 Self-Retaining / 320 mm
or	
03.010.152	Star / Hexdrive Screwdriver Shaft T25 3.5 mm Hex / Self-Retaining 280 mm
03.025.040	11.0 mm / 8.0 mm Protection Sleeve 188 mm for ASLS

Insert the appropriate 5.0 mm locking screw through the protection sleeve using the appropriate hexagonal or STARDRIVE Screwdriver.

Remove the protection sleeve and aiming arm.

■ Note:

If using retaining screws, please refer to addendum A for surgical technique and instruments.

Freehand Distal Locking – Long Nails

1. Distal locking

Distal locking of the long nail is performed with the freehand technique. Alternatively distal locking can be performed using the SURELOCK System and the corresponding technique guide.

■ Note:

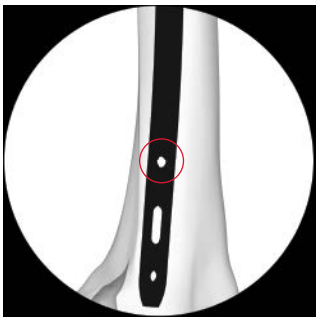
The SURELOCK System will only target the two most proximal distal locking holes in the long nail and only works with the Trochanteric Femoral Nails 280 mm to 460 mm in length.

There are three distal locking options:

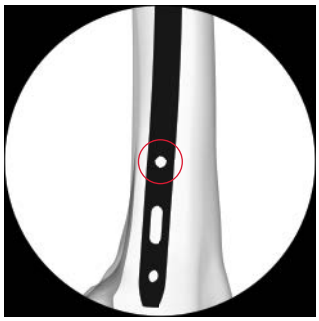
- Two transverse, lateral to medial holes
- One of the holes is static and the other allows for static or dynamic locking options
- One oblique locking hole for enhanced stability in trochanteric fractures with a shaft fracture. This is the most distal hole.

2. Align image

- Confirm reduction of the fracture with AP and lateral images.
- Align the image intensifier with the hole in the nail until a perfect circle is visible in the center of the screen.



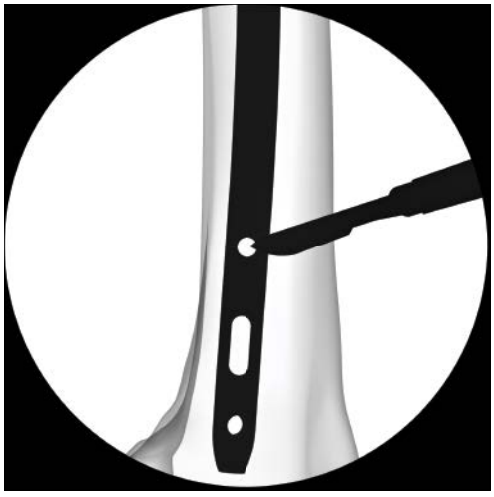
Not aligned.



Aligned.

3. Determine incision point

- Place a scalpel blade on the skin over the center of the hole to mark the incision point and make a stab incision.



4. Drill

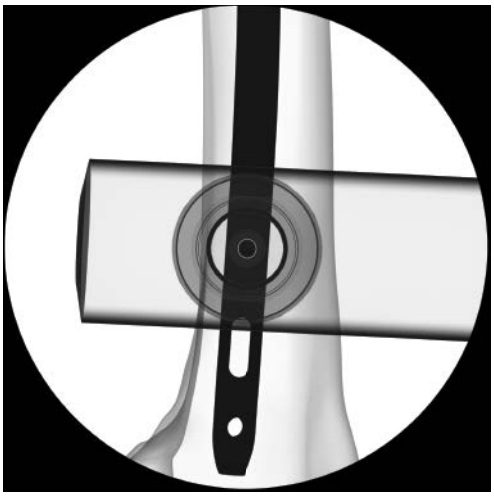
Instruments

03.010.101	4.2 mm Three-Fluted Radiolucent Drill Bit/Needle Point/145 mm
511.30	Radiolucent Drive Mark II

Insert the drill into the radiolucent drive and insert it, through the incision, down to the bone.

Incline the drive so that the tip of the drill bit is centered over the locking hole. The drill bit should almost completely fill the circle of the locking hole. Hold the drill bit in this position and drill through both cortices.

Stop drilling immediately after perforation of both cortices and disassemble the drill bit from the power equipment.



■ Note:

Before inserting the drill bit in the power tool, determine the right drilling position and fix the position with a light hammer tap on the back of the drill bit.

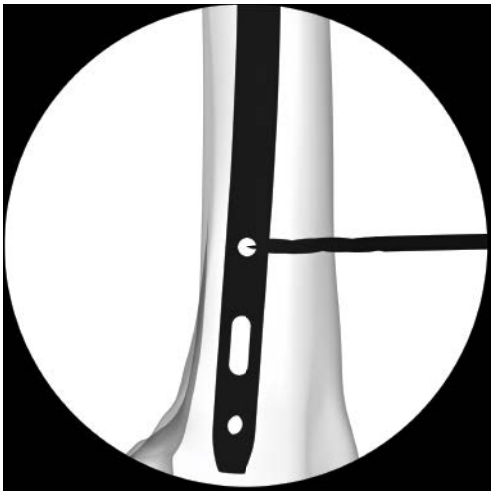
Alternative instrument

03.010.104	4.2 mm Three-Fluted Drill Bit QC/Needle Point/145 mm

■ Note:

For greater drill bit control, discontinue drill bit power after perforating the near cortex. Manually guide the drill bit through the nail before resuming power to drill the far cortex.

Stop drilling immediately after perforation of both cortices and disassemble the drill bit from the power equipment.



5. Measure for screw length

Instruments	
03.010.106	Direct Measuring Device for LCKNG SCR to 100 mm F / IM Nails
or	
03.010.429	Direct Measuring Device for LCKNG SCR to 100 mm F / IM Nails

Slide the measuring device onto the drill bit.

Ensure correct position of the drill bit beyond the far cortex, and that the measuring device is against the bone.

Read the measurement on the measuring device at the end of the drill bit, not from the green line.

■ Note:

Correct placement of the drill bit and measuring device are important for accurate locking screw length measurement.

Alternative instrument	
03.010.428	Depth Gauge for Locking Screws to 100 mm for IM Nails
or	
03.010.072	Depth Gauge for Locking Screws to 100 mm for IM Nails
or	
03.010.017	Depth Gauge for Locking Screws, measuring range up to 100 mm
or	
03.019.017	Depth Gauge for Locking Screws, measuring range up to 100 mm

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

Ensure the correct position of the depth gauge beyond the far cortex.

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

6. Insert locking screw

Instruments	
03.010.518	STARDRIVE Screwdriver / T25 Self-Retaining / 320 mm
03.010.473*	Inter-lock Screwdriver T25 / 3.5 mm Hex / 224 mm

■ Notes:

- If using retaining screws, please refer to addendum A for surgical technique and instruments.
- For Optional Nut and Washer Technique, please refer to addendum A.

Insert the appropriate length screw using the screwdriver.

Verify locking screw length under image intensification.

Repeat steps 2 to 6 for the second and third proximal locking screw if the fracture necessitates additional distal fixation.

*Also available.

Insert End Cap

1. Insert end cap

Instruments	
03.010.517	T-Handle Ball Hex Screwdriver 8 mm
03.010.520	Cannulated STARDRIVE Screwdriver / T40 / 277 mm
357.399	3.2 mm Guide Wire 400 mm
Alternative instruments	
03.045.018*	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm
03.043.027	Screw driver, hexagonal Ø 8.0 mm, with T-handle, spherical head

Use of an end cap is recommended if bony ingrowth into the proximal end of the nail is of concern. Also, in reverse oblique intertrochanteric and high subtrochanteric fractures, the nail should be slightly proud of the greater trochanter to provide an added point of fixation. If the nail has been over inserted, it should be extended by the use of an end cap of appropriate length.

Notes:

- The insertion depth of the nail is indicated by the rings on the insertion handle. Starting distally, each ring is an additional 5 mm from the tip of the nail. This will help in end cap selection.
- For use of retaining end cap, please refer to addendum A.

* Available non-sterile or sterile packed. Add “S” to the article number to order sterile products.

Inserting the 0 mm end cap

Remove the connecting screw using the ball hexagonal screwdriver while leaving the insertion handle connected to the nail.

Insert the 0 mm end cap using the cannulated STARDRIVE Screwdriver through the insertion handle. A 3.2 mm guide wire can be used to help ensure alignment while inserting the end cap.

After the end cap is inserted, remove the insertion handle from the nail.

Inserting the 5–15 mm end cap

Remove the connecting screw and insertion handle using the ball hexagonal screwdriver.

Insert the end cap using the cannulated STARDRIVE Screwdriver. A 3.2 mm guide wire can be used to help ensure alignment while inserting the end cap.

■ Note:

In case of difficulties to remove the connecting screw, push the insertion handle towards medial or lateral to neutralize soft tissue pressure.

Inserting the 0 mm end cap.

Inserting the 5–15 mm end cap.

Implant Removal

1. Disengage locking mechanism

Instruments	
03.037.028	5 mm Hex Flexible Screwdriver
03.037.030	Helical Blade / Screw Extractor
03.037.032	Nail Extractor
03.010.520	Cannulated STARDRIVE Screwdriver / T40 / 277 mm
356.717*	Guide Wire 2.8 mm Length 460 mm with Hook

■ Note:

Implant removal steps are consistent for both augmented and non-augmented hardware removal.

Use the cannulated STARDRIVE Screwdriver to remove the end cap, optionally assisted by use of the guide wire with hook.

In case of ingrown tissue or blockage with cement clean the recess with a sharp hook.

Turning counterclockwise, thread the helical blade / screw extractor into the end of the helical blade or screw. Do not yet extract the helical blade / screw.

Thread the nail extractor into the top of the nail. Pass the 5 mm hex flexible screwdriver through the nail extractor and engage the hex in the locking mechanism. Turn the locking mechanism counterclockwise until it stops. The locking mechanism is disengaged.

■ Note:

It may be easier to align the nail extractor if the flexible screwdriver is passed through the nail extractor first and then both instruments engage in the top of the nail.

▲ Precautions:

Do not attempt to remove the nail at this point.

Do not yet extract the screw / blade.

Do not yet extract the nail.

*Also available.

2. Remove helical blade or screw and distal locking screw

Instruments	
03.037.030	Helical Blade / Screw Extractor
03.010.522	Spiral Combination Hammer 500 Grams
03.010.518	STARDRIVE Screwdriver / T25 / Self Retaining / 320 mm
03.010.170*	Hammer Guide

Optional instrument

03.037.026 Helical Blade/Screw Coupling Screw

For the blade, slide the spiral combination hammer over the helical blade/screw extractor and using light hammer blows, hammer until the blade is removed from the bone.

■ Note:

The hammer guide may be threaded in the back of the helical blade / screw extractor to extend the working length and thus support the removal.

For the screw, continue to turn counterclockwise with a slight pulling force until the screw is removed from the bone.

Remove the distal locking screw using the screwdriver.

■ Notes:

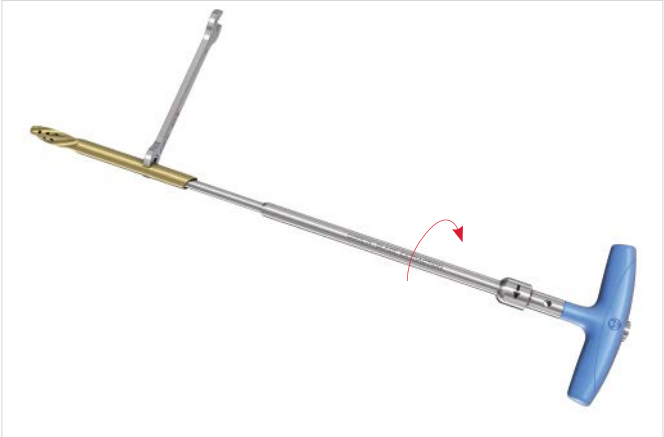
- **For the augmented blade, in the unlikely event that the TRAUMACEM V+ Injectable Bone Cement has filled the cannula covering the internal threads and thus preventing the Helical Blade/Screw Extractor from engaging the blade, thread the coupling screw into the back of the blade and finger tighten. Then attach the driving cap/threaded to the back of the coupling screw and use the spiral combination hammer (500g) to backslap if needed.**
- **For the augmented screw, in the unlikely event that the TRAUMACEM V+ Injectable Bone Cement has filled the cannula covering the internal threads and thus preventing the Helical Blade/Screw Extractor from engaging the screw, insert the cannulated coupling screw and thread in until fully captured in the screw inserter. The coupling screw will remain attached to the inserter. Align the inserter with the back end of the screw. Further thread the coupling screw into the screw and finger tighten the assembly. Turn the inserter counter clockwise with a slight pulling force to remove the screw.**

*Also available.

Remove helical blade or screw from the extractor

Instrument	
03.037.031	Combination Wrench 11 mm/Blade Screw

The end of the combination wrench marked “BLADE/ SCREW” can be attached to the blade or screw and then used to disengage the helical blade or screw from the helical blade/ screw extractor. Rotate clockwise as the blade and screw have a left-handed thread for removal.



3. Extract nail

Instruments	
03.010.170*	Hammer Guide
03.010.522	Spiral Combination Hammer 500 Grams

To remove the nail, thread the hammer guide onto the back end of the nail extractor. Attached the spiral combination hammer to the hammer guide and then use light hammer blows to extract the nail.

After the nail has been extracted from the bone, dissemble the extractor from the nail.

*Also available.

Alternative Technique – Extraction Hook for Removal of Broken Nail

Instruments	
355.399	Extraction Hook for TI Cannulated Nails*
393.10	Universal Chuck with T-Handle
Alternative instrument	
3.043.001	Universal Chuck

Begin with Steps 1 and 2 of Implant Removal.

Option 1

1. Assemble extraction hook and universal chuck

Insert the extraction hook into the universal chuck with T-Handle. The hook should be parallel with the T-Handle. This facilitates visualization of the hook position in the bone.

2. Insert extraction hook through nail

Remove the nail extractor and pass the extraction hook through the cannula of the nail, including the distant fragment.

■ Note:

Under image intensification, verify that the hook has passed through and engaged the distant end of the nail.

3. Extract nail

Extract both nail fragments.

■ Note:

Keep the patient's limb restrained to increase the efficiency of the extraction force.

*Also available.

Option 2

1. Remove near nail fragment

Remove the near nail fragment using the technique described in step 3 of the implant removal.

■ Note:

The extraction hook can be used as an alternative to extraction instrumentation.

2. Ream canal

Ream the medullary canal 1 mm larger than the nail diameter to clear a path for the distant nail fragment.

■ Note:

- Use image intensification to verify position/depth of the reamer to avoid contacting the distant nail fragment.

3. Align extraction hook

Insert the extraction hook and explanted near nail fragment into the medullary canal. The near nail fragment aligns the extraction hook with the cannulation of the distant nail fragment.

4. Engage distant fragment

Pass the extraction hook through the cannula of the distant nail fragment.

■ Note:

- **Under image intensification, verify that the hook has passed through and engaged the distant end of the nail.**

5. Extract nail

Extract both nail fragments.

■ Note:

Keep the patient's limb restrained to increase the efficiency of the extraction force.

Alternative Technique – Coupling Screw for Removal of Broken Nail

Instruments	
03.037.026	Helical Blade and Screw Coupling Screw

Optional instruments	
03.010.523	Driving cap threaded
03.010.522	Spiral Combination Hammer 500 Grams

■ Note:

The coupling screw may be used in instances where the nail is broken at the proximal hole and is in two pieces. For removal of the near fragment, use Steps 1 and 2 of Implant Removal. For removal of the distant nail fragment, this alternative technique may be used.

Begin with Steps 1 and 2 of Implant Removal.

1. Remove near nail fragment

Remove the near nail fragment using the technique described in step 3 of the implant removal.

2. Ream canal

Ream the proximal femur to 17 mm to clear a path for the distant nail fragment.

Note:

Use image intensification to verify position/depth of the reamer to avoid contacting the distant nail fragment.

3. Engage distant fragment

Thread the coupling screw into the distant nail fragment.

Notes:

- The coupling screw is cannulated. If the extraction hook is already in the nail, the coupling screw may be inserted over the extraction hook. Once the nail is engaged with the coupling screw, the extraction hook may be removed.
- A reaming rod may also be used to help guide the coupling screw into the nail thread. If using the reaming rod, insert the end opposite of the ball tip through the back of the coupling screw before inserting the reaming rod into the nail. This will allow guided insertion of the coupling screw and the ability to remove the reaming rod before attaching the threaded driving cap.
- Under image intensification, verify that the coupling screw has engaged the distant nail fragment.

4. Extract nail

If hammering is required to remove the distant nail fragment, remove the extraction hook or reaming rod if used, and attach the threaded driving cap into the back of the coupling screw for extraction. Slide the spiral combination hammer over the driving cap and using light hammer blows, hammer until the nail is removed from the bone.

Extract distant nail fragment.

Checking Drill Stop Wear

Instruments

03.037.022	6 mm / 9 mm Cannulated Stepped Drill Bit
03.037.023	Drill Stop for 03.037.022

Possible damage

If excessive wear occurs, the drill stop can slip, resulting in incorrect drilling depth.

Before use

- Slide the drill stop onto the drill bit
- Press on the stop with the thumb without pressing the button. If the stop moves under pressure, replace it
- Do the same test in the opposite direction. If the stop moves, replace it

Recommendations

- Drill only under periodic image intensifier control
- While drilling, do not force
- Replace drill stops that do not pass the described wear test

TFN-ADVANCED Proximal Femoral Nailing System, Long Nails

Features of the long 9 mm–14 mm Cannulated Nails, 300 mm–480 mm lengths (20 mm increments)

- Proximal diameter of 15.66 mm
- Anatomic 5° lateral angle
- Distal diameters of 9 mm, 10 mm, 11 mm, 12 mm, and 14 mm
- Preassembled locking mechanism for controlling blade rotation and amount of blade travel
- Anterior Posterior bend—1.0 m radius of curvature
- Static or dynamic interlocking with controlled dynamization of 10 mm
- Anatomic 10° anteversion
- Third distal locking hole is 10° offset from superior, anterior lateral to posterior medial
- Nail designs for both left and right femurs

Material

- Ti-15Mo (TiMo)
- Green

Locking mechanism

- TAN, CoCr

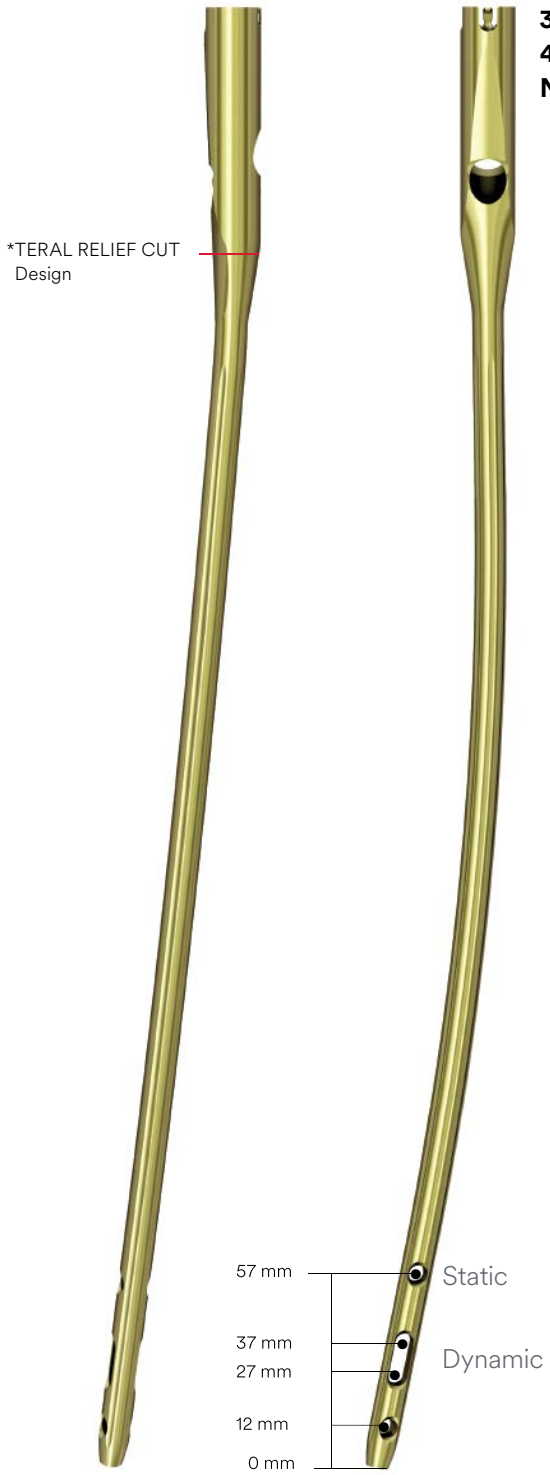
Angles

- 125°, 130° and 135°

Distal locking

- 5.0 mm locking screws, hex or STARDRIVE Recess

TFNA Nail Dia.	LATERAL RELIEF CUT™ Design*
9 mm	13.4 mm
10 mm	13.7 mm
11 mm	14.1 mm
12 mm	14.5 mm
14 mm	15.2 mm



TFN-ADVANCED System, Long Nails, 9 mm distal diameter, sterile

Right	Left	Length (mm)	Femoral Neck Angle
04.037.916S	04.037.917S	260	125°
04.037.918S	04.037.919S	280	125°
04.037.920S	04.037.921S	300	125°
04.037.922S	04.037.923S	320	125°
04.037.924S	04.037.925S	340	125°
04.037.926S	04.037.927S	360	125°
04.037.928S	04.037.929S	380	125°
04.037.930S	04.037.931S	400	125°
04.037.932S	04.037.933S	420	125°
04.037.934S	04.037.935S	440	125°
04.037.936S	04.037.937S	460	125°
04.037.938S	04.037.939S	480	125°
04.037.946S	04.037.947S	260	130°
04.037.948S	04.037.949S	280	130°
04.037.950S	04.037.951S	300	130°
04.037.952S	04.037.953S	320	130°
04.037.954S	04.037.955S	340	130°
04.037.956S	04.037.957S	360	130°
04.037.958S	04.037.959S	380	130°
04.037.960S	04.037.961S	400	130°
04.037.962S	04.037.963S	420	130°
04.037.964S	04.037.965S	440	130°
04.037.966S	04.037.967S	460	130°
04.037.968S	04.037.969S	480	130°

TFN-ADVANCED System, Long Nails, 10 mm distal diameter, sterile

Right	Left	Length (mm)	Femoral Neck Angle
04.037.016S	04.037.017S	260	125°
04.037.018S	04.037.019S	280	125°
04.037.020S	04.037.021S	300	125°
04.037.022S	04.037.023S	320	125°
04.037.024S	04.037.025S	340	125°
04.037.026S	04.037.027S	360	125°
04.037.028S	04.037.029S	380	125°
04.037.030S	04.037.031S	400	125°
04.037.032S	04.037.033S	420	125°
04.037.034S	04.037.035S	440	125°
04.037.036S	04.037.037S	460	125°
04.037.038S	04.037.039S	480	125°
04.037.046S	04.037.047S	260	130°
04.037.048S	04.037.049S	280	130°
04.037.050S	04.037.051S	300	130°
04.037.052S	04.037.053S	320	130°
04.037.054S	04.037.055S	340	130°
04.037.056S	04.037.057S	360	130°
04.037.058S	04.037.059S	380	130°
04.037.060S	04.037.061S	400	130°
04.037.062S	04.037.063S	420	130°
04.037.064S	04.037.065S	440	130°
04.037.066S	04.037.067S	460	130°
04.037.068S	04.037.069S	480	130°

Note: For additional information, please refer to package insert or www.e-ifu.com

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

TFN-ADVANCED System, Long Nails, 11 mm distal diameter, sterile

Right	Left	Length (mm)	Femoral Neck Angle
04.037.120S	04.037.121S	300	125°
04.037.122S	04.037.123S	320	125°
04.037.124S	04.037.125S	340	125°
04.037.126S	04.037.127S	360	125°
04.037.128S	04.037.129S	380	125°
04.037.130S	04.037.131S	400	125°
04.037.132S	04.037.133S	420	125°
04.037.134S	04.037.135S	440	125°
04.037.136S	04.037.137S	460	125°
04.037.138S	04.037.139S	480	125°
04.037.150S	04.037.151S	300	130°
04.037.152S	04.037.153S	320	130°
04.037.154S	04.037.155S	340	130°
04.037.156S	04.037.157S	360	130°
04.037.158S	04.037.159S	380	130°
04.037.160S	04.037.161S	400	130°
04.037.162S	04.037.163S	420	130°
04.037.164S	04.037.165S	440	130°
04.037.166S	04.037.167S	460	130°
04.037.168S	04.037.169S	480	130°
04.037.180S	04.037.181S	300	135°
04.037.182S	04.037.183S	320	135°
04.037.184S	04.037.185S	340	135°
04.037.186S	04.037.187S	360	135°
04.037.188S	04.037.189S	380	135°
04.037.190S	04.037.191S	400	135°
04.037.192S	04.037.193S	420	135°
04.037.194S	04.037.195S	440	135°
04.037.196S	04.037.197S	460	135°
04.037.198S	04.037.199S	480	135°

TFN-ADVANCED System, Long Nails, 12 mm distal diameter, sterile

Right	Left	Length (mm)	Femoral Neck Angle
04.037.220S	04.037.221S	300	125°
04.037.222S	04.037.223S	320	125°
04.037.224S	04.037.225S	340	125°
04.037.226S	04.037.227S	360	125°
04.037.228S	04.037.229S	380	125°
04.037.230S	04.037.231S	400	125°
04.037.232S	04.037.233S	420	125°
04.037.234S	04.037.235S	440	125°
04.037.236S	04.037.237S	460	125°
04.037.238S	04.037.239S	480	125°
04.037.250S	04.037.251S	300	130°
04.037.252S	04.037.253S	320	130°
04.037.254S	04.037.255S	340	130°
04.037.256S	04.037.257S	360	130°
04.037.258S	04.037.259S	380	130°
04.037.260S	04.037.261S	400	130°
04.037.262S	04.037.263S	420	130°
04.037.264S	04.037.265S	440	130°
04.037.266S	04.037.267S	460	130°
04.037.268S	04.037.269S	480	130°

TFN-ADVANCED System, Long Nails, 14 mm distal diameter, sterile

Right	Left	Length (mm)	Femoral Neck Angle
04.037.450S	04.037.451S	300	130°
04.037.452S	04.037.453S	320	130°
04.037.454S	04.037.455S	340	130°
04.037.456S	04.037.457S	360	130°
04.037.458S	04.037.459S	380	130°
04.037.460S	04.037.461S	400	130°
04.037.462S	04.037.463S	420	130°
04.037.464S	04.037.465S	440	130°
04.037.466S	04.037.467S	460	130°
04.037.468S	04.037.469S	480	130°

TFN-ADVANCED Proximal Femoral Nailing System, Short Nails

Features of the short 9 mm–12 mm Cannulated Nails, 170 mm, 200 mm and 235 mm lengths

- Proximal diameter of 15.66 mm
- Anatomic 5° lateral angle
- Distal diameters of 9 mm, 10 mm, 11 mm, and 12 mm
- Preassembled locking mechanism for controlling blade or screw rotation and amount of blade or screw travel
- Static interlocking

Material

- Ti-15Mo (TiMo)
- Green

Locking mechanism

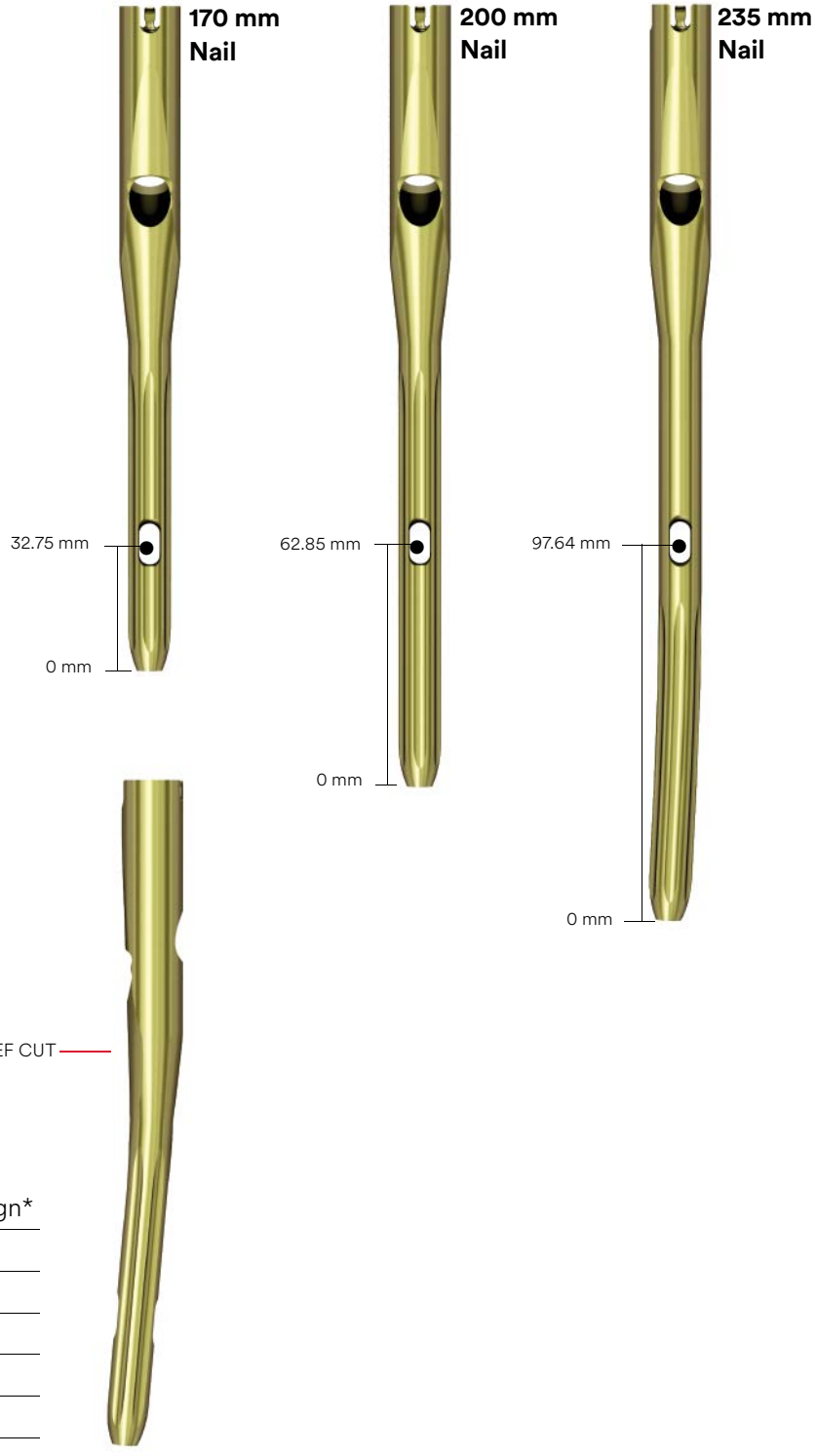
- TAN, CoCr

Angles

- 125°, 130° and 135°

Distal locking

- 5.0 mm locking screws, hex or STARDRIVE Recess



TFNA Nail Dia.	LATERAL RELIEF CUT Design*
9 mm	13.4 mm
10 mm	13.7 mm
11 mm	14.1 mm
12 mm	14.5 mm
14 mm	15.2 mm

TFN-ADVANCED System, Short Nails, 170 mm length, sterile

	Dia. (mm)	Femoral Neck Angle
04.037.912S	9	125°
04.037.942S	9	130°
04.037.972S	9	135°
04.037.012S	10	125°
04.037.042S	10	130°
04.037.072S	10	135°
04.037.112S	11	125°
04.037.142S	11	130°
04.037.172S	11	135°
04.037.212S	12	125°
04.037.242S	12	130°
04.037.272S	12	135°

TFN-ADVANCED System, Short Nails, 200 mm length, sterile

	Dia. (mm)	Femoral Neck Angle
04.037.913S	9	125°
04.037.943S	9	130°
04.037.973S	9	135°
04.037.013S	10	125°
04.037.043S	10	130°
04.037.073S	10	135°
04.037.113S	11	125°
04.037.143S	11	130°
04.037.173S	11	135°
04.037.213S	12	125°
04.037.243S	12	130°
04.037.273S	12	135°

TFN-ADVANCED System, Short Nails, 235 mm length, sterile

Right	Left	Dia. (mm)	Femoral Neck Angle
04.037.914S	04.037.915S	9	125°
04.037.944S	04.037.945S	9	130°
04.037.974S	04.037.975S	9	135°
04.037.014S	04.037.015S	10	125°
04.037.044S	04.037.045S	10	130°
04.037.074S	04.037.075S	10	135°
04.037.114S	04.037.115S	11	125°
04.037.144S	04.037.145S	11	130°
04.037.174S	04.037.175S	11	135°
04.037.214S	04.037.215S	12	125°
04.037.244S	04.037.245S	12	130°
04.037.274S	04.037.275S	12	135°

Head Elements

TFNA Screws◊

- Ti-6Al-7Nb (TAN)
- Color: gold
- 10.35 mm diameter
- 70 mm–130 mm
- Cannulated

TFNA Helical Blades◊

- Ti-6Al-7Nb (TAN)
- Color: gold
- 70 mm–130 mm (5 mm increments)
- 10.35 mm diameter
- Cannulated

Titanium Screws

	Length (mm)		Length (mm)
04.038.170	70	04.038.205	105
04.038.175	75	04.038.210	110
04.038.180	80	04.038.215	115
04.038.185	85	04.038.220	120
04.038.190	90	04.038.225	125
04.038.195	95	04.038.230	130
04.038.200	100		

Titanium Helical Blades

	Length (mm)		Length (mm)
04.038.370	70	04.038.405	105
04.038.375	75	04.038.410	110
04.038.380	80	04.038.415	115
04.038.385	85	04.038.420	120
04.038.390	90	04.038.425	125
04.038.395	95	04.038.430	130
04.038.400	100		

◊Available nonsterile or sterile-packed.

Add “S” to catalog number to order sterile product.

Titanium End Caps for TFN-ADVANCED Nail, sterile

- Ti-6Al-7Nb (TAN)
- Color: green
- 0 mm (sits flush with nail end)
- 5 mm / 10 mm and 15 mm extensions
- STARDRIVE Recess T40, hexagonal recess 5.0 mm

15 mm 10 mm 5 mm 0 mm

	Extension
04.038.000S	0 mm
04.038.005S	5 mm
04.038.010S	10 mm
04.038.015S	15 mm

Titanium retaining end caps for TFN-ADVANCED Nail, sterile

- Ti-6Al-7Nb (TAN)
- Color: green
- 0 mm (sits flush with nail end)
- 5 mm/10 mm and 15 mm extensions
- XL40 recess

15 mm 10 mm 5 mm 0 mm

	Extension
04.045.870S	0 mm
04.045.875S	5 mm
04.045.880S	10 mm
04.045.885S	15 mm

Screws Used with the TFN-ADVANCED Proximal Femoral Nailing System

5.0 mm Ti Locking Screws with T25 STARDRIVE Recess for IM Nails◊

- Ti-6Al-7Nb (TAN)
- Light green
- 4.2 mm diameter drill
- 26 mm – 80 mm (2 mm increments)
  80 mm – 100 mm (5 mm increments)
- STARDRIVE Recess T25

5.0 mm Titanium Locking Screws with Hexagonal Drive◊

- Ti-6Al-7Nb (TAN)
- Light green
- 4.2 mm diameter drill
- 26 mm – 80 mm (2 mm increments)
  80 mm – 100 mm (5 mm increments)
- 3.5 hexagonal recess

5.0 mm Ti Locking Screws with T25 StarDrive Recess for IM Nails◊

	Length (mm)		Length (mm)
04.005.516	26 mm	04.005.542	52 mm
04.005.518	28 mm	04.005.544	54 mm
04.005.520	30 mm	04.005.546	56 mm
04.005.522	32 mm	04.005.548	58 mm
04.005.524	34 mm	04.005.550	60 mm
04.005.526	36 mm	04.005.554	64 mm
04.005.528	38 mm	04.005.558	68 mm
04.005.530	40 mm	04.005.562	72 mm
04.005.532	42 mm	04.005.566	76 mm
04.005.534	44 mm	04.005.570	80 mm
04.005.536	46 mm	04.005.575	85 mm
04.005.538	48 mm	04.005.580	90 mm
04.005.540	50 mm		

5.0 mm Titanium Locking Screws with Hexagonal Drive◊

	Length (mm)		Length (mm)
458.926	26 mm	458.952	52 mm
458.928	28 mm	458.954	54 mm
458.930	30 mm	458.956	56 mm
458.932	32 mm	458.958	58 mm
458.934	34 mm	458.960	60 mm
458.936	36 mm	458.964	64 mm
458.938	38 mm	458.968	68 mm
458.940	40 mm	458.972	72 mm
458.942	42 mm	458.976	76 mm
458.944	44 mm	458.980	80 mm
458.946	46 mm	458.985	85 mm
458.948	48 mm	458.990	90 mm
458.950	50 mm		

◊All screws available non-sterile or in sterile packaging. Two different sterile packaging available: sterile tube packaging (corresponding article number with suffix “TS”) and standard sterile packaging (corresponding article number with suffix “S”).

Locking Screws for Medullary Nails

- Ti-6Al-7Nb (TAN)
- Light green
- 4.2 mm diameter drill
- 26 mm – 88 mm (2 mm increments)
  90-120 mm (5 mm increments)
- XL25 recess

Standard Locking Screw

Low-Profile Locking Screw

Locking Screws for Medullary Nail*, ∅ 5 mm

	Length (mm)		Length (mm)
04.045.026	26	04.045.066	66
04.045.028	28	04.045.068	68
04.045.030	30	04.045.070	70
04.045.032	32	04.045.072	72
04.045.034	34	04.045.074	74
04.045.036	36	04.045.076	76
04.045.038	38	04.045.078	78
04.045.040	40	04.045.080	80
04.045.042	42	04.045.082	82
04.045.044	44	04.045.084	84
04.045.046	46	04.045.086	86
04.045.048	48	04.045.088	88
04.045.050	50	04.045.090	90
04.045.052	52	04.045.095	95
04.045.054	54	04.045.100	100
04.045.056	56	04.045.105	105
04.045.058	58	04.045.110	110
04.045.060	60	04.045.115	115
04.045.062	62	04.045.120	120
04.045.064	64		

Low-Profile Locking Screws for Medullary Nail*, ∅ 5 mm

	Length (mm)		Length (mm)
04.045.326	26	04.045.366	66
04.045.328	28	04.045.368	68
04.045.330	30	04.045.370	70
04.045.332	32	04.045.372	72
04.045.334	34	04.045.374	74
04.045.336	36	04.045.376	76
04.045.338	38	04.045.378	78
04.045.340	40	04.045.380	80
04.045.342	42	04.045.382	82
04.045.344	44	04.045.384	84
04.045.346	46	04.045.386	86
04.045.348	48	04.045.388	88
04.045.350	50	04.045.390	90
04.045.352	52	04.045.395	95
04.045.354	54	04.045.400	100
04.045.356	56	04.045.405	105
04.045.358	58	04.045.410	110
04.045.360	60	04.045.415	115
04.045.362	62	04.045.420	120
04.045.364	64		

*All screws available non-sterile or in sterile tube packaging (corresponding article number with suffix “TS”). Additionally, all screws 84mm or longer also available in standard sterile packaging (corresponding article number with suffix “S”).

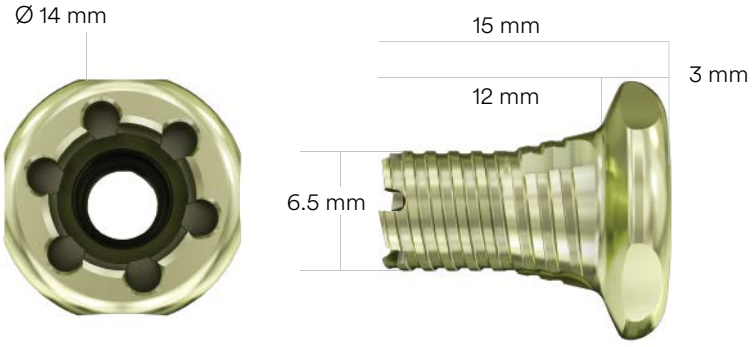
Titanium Nuts and Washers for Locking Screws

Titanium Nuts and Washers for Locking Screws

- Nuts are made of Titanium alloy, Washers are made of titanium.
- Nut is inserted over standard locking screws, either at the screw tip or screw head
- Washer for Nut, 1.1 mm thickness, to increase overall diameter to 17 mm
- Washer for Screw, 1.2 mm thickness, to increase diameter without uses of nut to 14 mm

04.045.780S	Washer for Screw
04.045.781S	Nut
04.045.782S	Washer for Nut

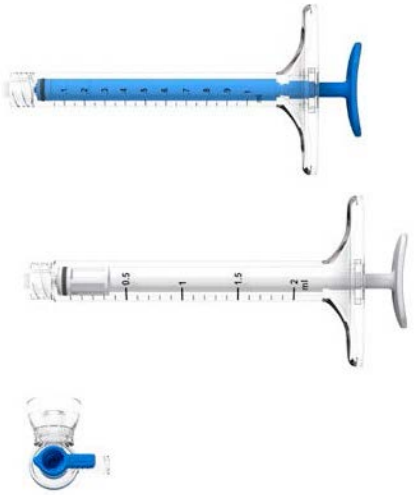
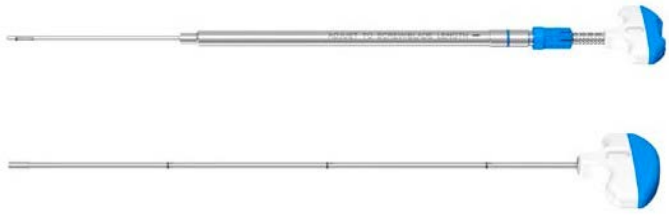
04.045.780S



04.045.781S

04.045.782S

Implants and Instruments for TRAUMACEM V+ Augmentation System

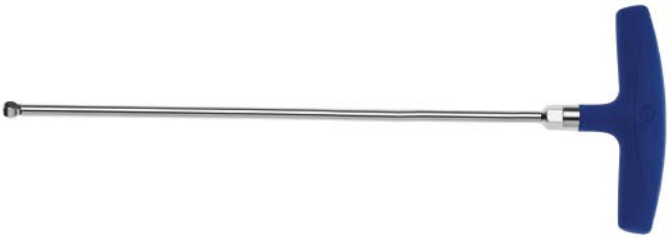
07.702.040S	TRAUMACEM V+ Injectable Bone Cement, sterile Containing: 1 × TRAUMACEM V+ mixer with sterilization lid 1 × Monomer glass ampoule 1 × Cement mixing and transferring lid	
03.702.150S	TRAUMACEM V+ Syringe Kit, 4 x 1 mL, 2 x 2 mL, sterile Containing: 4 × Blue 1 mL syringes 2 × White 2 mL syringes 1 × One-way stopcock	
03.702.121S	TRAUMACEM V+ Injection Cannula, for TFNA System, sterile Containing: 1 × Side-opening cannula, with Luer-lock 1 × Plunger	

Additionally required:
1–2 Syringes with Luer lock
Radiographic contrast agent
Saline solution

Instruments

03.010.061	4.2 mm Three-Fluted Drill Bit quick coupling, 330 mm, 100 mm calibration	
03.010.065	8.0 mm/4.2 mm Drill Sleeve 200 mm	
03.010.070	4.2 mm Trocar 210 mm	
03.010.072	Depth Gauge for Locking Screws to 100 mm for IM Nails	
03.010.093	Reaming Rod Push Rod with Ball Handle	
03.010.101	4.2 mm Three-Fluted Drill Bit, calibrated, with Coupling for RDL, 145 mm	
03.010.104	4.2 mm Three-Fluted Drill Bit quick coupling, needle point, 145 mm	
03.010.106	Direct Measuring Device for Locking Screws to 100 mm for IM Nails	

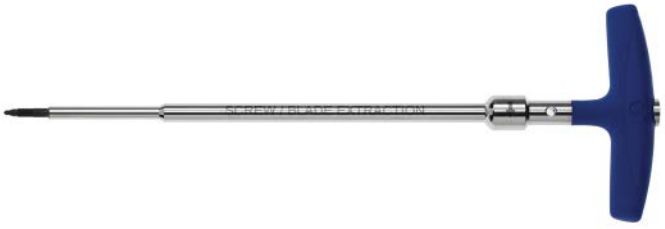
03.010.151	Star/HexDrive Screwdriver Shaft T25, 3.5 mm Hexagonal self-retaining, quick coupling, 165 mm	
03.010.152	Star/HexDrive Screwdriver Shaft T25, 3.5 mm Hexagonal self-retaining, quick coupling, 280 mm	
03.010.170	Hammer Guide	
03.010.412	Guide Wire Aiming Device for Trochanteric Fixation Nail for Anterior Posterior orientation	
03.010.415	Connecting Screw for Guide Wire Aiming Device for Trochanteric Fixation Nail, Anterior Posterior orientation	
03.010.429	Direct Measuring Device for Drill Bits, 145 mm	
03.010.471	Guide Wire Aiming Device Offset Block	
03.010.473	Inter-lock Screwdriver T25 StarDrive/ 3.5 mm Hexagonal, 224 mm	

03.010.491	Long Scalpel Handle	
03.010.494	Depth Gauge for Locking Screws to 100 mm	
03.010.495	Intramedullary Reduction Tool, curved, with Quick Coupling, Hex 12 mm	
03.010.496	T-Handle Cannulated, with Quick Coupling	
03.010.500	Handle, with Quick Coupling	
03.010.517	T-Handle Ball Hex Screwdriver 8 mm	
03.010.518	Screwdriver self-retaining, T25, 320 mm	
03.010.520	Screwdriver T40, 277 mm	

03.010.522	Spiral Combination Hammer 500 grams	
03.010.523	Driving Cap threaded	
03.025.040	11.0 mm/8.0 mm Protection Sleeve 188 mm for Angular Stable Locking System	
03.037.000	Multi Hole Wire Guide 136 mm	
03.037.001	16 mm Protection Sleeve 118 mm	
03.037.002	16 mm Cannulated Flexible Drill Bit Large Quick Coupling–266 mm	
03.037.008	8 mm Cannulated Curved Awl	
03.037.010	Cannulated Connecting Screw	

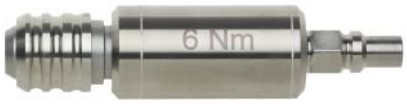
03.037.012	Complete Radiolucent Insertion Handle	
03.037.013	130 Degree Aiming Arm	
03.037.014	125 Degree Aiming Arm	
03.037.015	Aiming Arm Locking Device	
03.037.016	Buttress Compression Nut	
03.037.017	Blade/Screw Guide Sleeve	
03.037.018	3.2 mm Wire Guide Sleeve 248 mm	
03.037.019	3.2 mm Trocar 270 mm	

03.037.020	Helical Blade and Screw Measuring Device	
03.037.021	10 mm Cannulated Tapered Drill Bit large quick coupling, 300 mm	
03.037.022	6 mm/9 mm Cannulated Stepped Drill Bit large quick coupling, 500 mm	
03.037.023	Drill Stop for use with 6 mm/9 mm cannulated stepped drill bit (03.037.022)	
03.037.024	Helical Blade Inserter for Trochanteric Fixation Nail Advanced	
03.037.025	Screw Inserter	
03.037.026	Helical Blade and Screw Coupling Screw	

03.037.027	Tap for Screw	
03.037.028	5 mm Hexagonal Flexible Screwdriver	
03.037.029	5 mm Hexagonal Screwdriver Shaft	
03.037.030	Helical Blade and Screw Extractor for use with Trochanteric Fixation Nail Advanced System	
03.037.031	Combination Wrench 11 mm for blade and screws	
03.037.032	Nail Extractor	
03.037.036	Depth Gauge for Trochanteric Nailing System	

03.037.116	Compression Nut for use with Trochanteric Fixation Nail Advanced Screw Inserter	
03.037.120	Threaded Hammer Guide Connector	
03.043.001	Universal Chuck	
03.043.027	Screw driver, hexagonal ∅ 8.0 mm, with T-handle, spherical head	
03.045.001	Screwdriver XL25	
03.045.002	Retention Pin for Screwdriver XL25	
03.045.003	Screwdriver, short, XL25	
03.045.004	Retention Pin for Screwdriver, short	

03.045.005	Screwdriver XL25 Quick Coupling Hex 12 mm	
03.045.006	Retention Pin for Screwdriver Quick Coupling, Hex 12 mm	
03.045.007	Screwdriver, short, XL25 Quick Coupling Hex 12 mm	
03.045.008	Retention Pin for Screwdriver, short, Quick Coupling Hex 12 mm	
03.045.009	Sleeve for screwdriver	
03.045.010	Sleeve for screwdriver, short	
03.045.011	Screwdriver XL40	
03.045.012	Retention Pin for Screwdriver XL40	
03.045.018	Guide Wire Ø 3.2 mm, w/ drill tip, 400 mm	

03.045.019	Protection Sleeve, Ø 11/8	
03.045.020	Drill Sleeve, Ø 4.2 mm	
03.045.022	Drill Bit Ø 4.2 mm, calibrated, 120 mm	
03.045.029	Reamer, ∅ 5.5 mm	
03.045.035	Direct measuring device for IM nails	
03.045.036	Tube for Direct measuring device Insert image for instrument	
03.140.023	Torque Limiting Attachment 6Nm for AO Reaming Coupler	
03.140.027	Handle, large, cannulated, with Quick Coupling, Hex 12 mm	

292.12	Kirshner Wire 1.25 mm w/ trocar tip, 150 mm	
321.16	Combination Wrench 11 mm	
321.17	4.5 mm Pin Wrench 120 mm	
351.717	Depth Gauge for Medullary Nails	
351.719	Depth Gauge Extension Tube for use with 351.717 or 03.019.001	
357.399	3.2 mm Guide Wire 400 mm	
357.413	5.6 mm/3.2 mm Drill Guide 198 mm	
357.415	5.0 mm Hexagonal Shaft 210 mm	
393.10	Universal Chuck with T-Handle	

Also Available

03.037.003	16 mm Cannulated Drill Bit	
03.037.004	16 mm Cannulated Hollow Drill Bit large quick coupling, 214 mm	
03.037.005	Reamer Protection Tube	
03.037.105	Trocar for Protection Tube	
03.037.011	Hybrid Insertion Handle	
03.037.115	130 Degree Screw Only Aiming Arm	

03.037.035	135 Degree Aiming Arm for Static Distal Locking	
03.045.030	Extractor Shaft for XL25	
03.045.031	Curette for XL25	
03.045.032	Extraction Screw, conical	
03.900.001	Straight Sharp Hook	

TFNA Standard Instrument Set (01.037.000)

Graphic Cases

60.037.002	Full Length Graphic Case 2-high
60.037.003	Full Length Graphic Case 3-high
60.037.020	Opening Tray for TFN-ADVANCED
60.037.021	Nail Insertion Tray for TFN-ADVANCED
60.037.022	Blade/Screw Insertion Tray for TFN-ADVANCED
60.037.023	Locking Tray for TFN-ADVANCED
60.037.011	TFNA Complete Set Graphic Case Label Sheet

Instruments

03.010.061	4.2 mm Three-Fluted Drill Bit quick coupling, 330 mm, 100 mm calibration
03.010.065	8.0 mm/4.2 mm Drill Sleeve 200 mm
03.010.070	4.2 mm Trocar 210 mm
03.010.072	Depth Gauge for Locking Screws to 100 mm for IM Nails
03.010.093	Reaming Rod Push Rod with Ball Handle
03.010.104	4.2 mm Three-Fluted Drill Bit quick coupling, needle point, 145 mm
03.010.106	Direct Measuring Device for Locking Screws to 100 mm for IM Nails
03.010.151	Star/HexDrive Screwdriver Shaft T25, 3.5 mm Hexagonal self-retaining, quick coupling, 165 mm
03.010.152	Star/HexDrive Screwdriver Shaft T25, 3.5 mm Hexagonal self-retaining, quick coupling, 280 mm
03.010.170	Hammer Guide
03.010.412	Guide Wire Aiming Device for Trochanteric Fixation Nail for Anterior Posterior orientation
03.010.415	Connecting Screw for Guide Wire Aiming Device for Trochanteric Fixation Nail, Anterior Posterior orientation

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

03.010.471	Guide Wire Aiming Device Offset Block
03.010.473	Inter-lock Screwdriver T25 StarDrive/ 3.5 mm Hexagonal, 224 mm
03.010.491	Long Scalpel Handle
03.010.496	T-Handle Cannulated, with quick coupling
03.010.517	T-Handle Ball Hex Screwdriver 8 mm
03.010.518	Screwdriver self retaining, T25, 319 mm
03.010.520	Screwdriver T40, 277 mm
03.010.522	Spiral Combination Hammer 500 grams
03.010.523	Driving Cap threaded
03.025.040	11.0 mm/8.0 mm Protection Sleeve 188 mm for Angular Stable Locking System
03.037.000	Multi Hole Wire Guide 136 mm
03.037.001	16 mm Protection Sleeve 118 mm
03.037.002	16 mm Cannulated Flexible Drill Bit Large Quick Coupling - 266 mm
03.037.003	16 mm Cannulated Drill Bit Large Quick Coupling - 266 mm
03.037.005	Reamer Protection Tube 160 mm
03.037.006	Radiographic Ruler
03.037.008	8 mm Cannulated Curved AWL
03.037.010	Cannulated Connecting Screw, 2 ea.
03.037.012	Complete Radiolucent Insertion Handle
03.037.013	130 Degree Aiming Arm
03.037.015	Aiming Arm Locking Device
03.037.016	Buttress Compression Nut
03.037.017	Blade/Screw Guide Sleeve
03.037.018	3.2 mm Wire Guide Sleeve 248 mm
03.037.019	3.2 mm Trocar 270 mm
03.037.020	Helical Blade and Screw Measuring Device
03.037.021	10 mm Cannulated Tapered Drill Bit large quick coupling, 300 mm
03.037.022	6 mm/9 mm Cannulated Stepped Drill Bit large quick coupling, 500 mm
03.037.023	Drill Stop for use with 6 mm/9 mm cannulated stepped drill bit (03.037.022)
03.037.024	Helical Blade Inserter for Trochanteric Fixation Nail Advanced
03.037.025	Screw Inserter
03.037.026	Helical Blade and Screw Coupling Screw
03.037.027	Tap for Screw
03.037.028	5 mm Hexagonal Flexible Screwdriver
03.037.029	5 mm Hexagonal Screwdriver Shaft
03.037.030	Helical Blade and Screw Extractor
03.037.031	Combination Wrench 11 mm for blade and screws
03.037.032	Nail Extractor
03.037.036	Depth Gauge for Trochanteric Nailing System
03.037.105	Trocar For Protection Tube
03.037.116	Compression Nut
03.037.120	Threaded Hammer Guide Connector, 2 ea.
03.140.023	Torque Limiting Attachment 6Nm for AO Reaming Coupler
321.17	4.5 mm Pin Wrench 120 mm
351.719	Depth Gauge Extension Tube for use with 351.717 or 03.019.001
357.399	3.2 mm Guide Wire 400 mm, 10 ea.
357.413	5.6 mm/3.2 mm Drill Guide 198 mm, 2 ea.
357.415	5.0 mm Hexagonal Shaft 210 mm
393.10	Universal Chuck with T-Handle

Graphic Cases

60.037.001	Full Length Graphic Case 1-high
60.037.024	Percutaneous Instrument Tray for TFN-ADVANCED

Instruments

09.037.010	3.2 mm Guide Wire 475 mm, 5 ea.
03.037.100	Percutaneous Multi Hole Wire Guide 260 mm
03.037.101	16 mm Percutaneous Sleeve 242 mm
03.037.102	16 mm Cannulated Percutaneous Flexible Drill Bit large quick coupling, 390 mm
03.037.103	16 mm Cannulated Percutaneous Drill Bit large quick coupling, 390 mm
03.037.112	Percutaneous Radiolucent Insertion Handle

TFN-ADVANCED Implant Set (01.037.002)

Graphic Cases

60.037.001	Graphic Case/Full Length 1-high
60.037.026	TFNA Implant Tray for TFN-ADVANCED
60.037.011	TFN-ADVANCED Complete Set Graphic Case Label Sheet

Instruments

319.97	Screw Forceps

Implants

TFN-ADVANCED Helical Blades◊

	Length (mm)		Length (mm)
04.038.370	70 mm	04.038.405	105 mm
04.038.375	75 mm	04.038.410	110 mm
04.038.380	80 mm	04.038.415	115 mm
04.038.385	85 mm	04.038.420	120 mm
04.038.390	90 mm	04.038.425	125 mm
04.038.395	95 mm	04.038.430	130 mm
04.038.400	100 mm		

TFN-ADVANCED Screws◊

	Length (mm)		Length (mm)
04.038.170	70 mm	04.038.205	105 mm
04.038.175	75 mm	04.038.210	110 mm
04.038.180	80 mm	04.038.215	115 mm
04.038.185	85 mm	04.038.220	120 mm
04.038.190	90 mm	04.038.225	125 mm
04.038.195	95 mm	04.038.230	130 mm
04.038.200	100 mm		

5.0 mm Ti Locking Screws with T25 STARDRIVE Recess for IM Nails, 2 ea.◊

	Length (mm)		Length (mm)
04.005.516	26 mm	04.005.542	52 mm
04.005.518	28 mm	04.005.544	54 mm
04.005.520	30 mm	04.005.546	56 mm
04.005.522	32 mm	04.005.548	58 mm
04.005.524	34 mm	04.005.550	60 mm
04.005.526	36 mm	04.005.554	64 mm
04.005.528	38 mm	04.005.558	68 mm
04.005.530	40 mm	04.005.562	72 mm
04.005.532	42 mm	04.005.566	76 mm
04.005.534	44 mm	04.005.570	80 mm
04.005.536	46 mm	04.005.575	85 mm
04.005.538	48 mm	04.005.580	90 mm
04.005.540	50 mm		

◊Available nonsterile or sterile-packed. Add “S” to catalog number to order sterile product.

Also Available

Sets

01.004.306	Flexible Reamer Set, Long
01.010.201	SureLock Instrument Set
01.116.041	Reduction Instrument Set with MIPO complete
01.037.002	TFNA Implant Set
01.037.003	TFNA Basic Blade Instrument Set
01.037.004	TFNA Screw Only Set
01.037.005	TFNA Basic Removal Instrument Set
01.116.042	Reduction Instrument Set complete
105.309	Reamer/Irrigator/Aspirator Set
150.060	Flexible Reamer Set for IM Nails

Instruments

03.010.428	Depth Gauge for Locking Screws to 100 mm for IM Nails
03.231.018	6Nm Torque Limiting Blue Handle with 6 mm Hex Coupling
03.019.017	Depth Gauge for Locking Screws, measuring range to 100 mm
03.037.003	16 mm Cannulated Drill Bit
03.037.005	Reamer Protection Tube
03.037.006	Radiographic Ruler
03.037.105	Trocar for Protection Tube
03.037.011	Hybrid Insertion Handle
351.706S	2.5 mm Reaming Rod with ball tip, 950 mm, sterile
351.707S	2.5 mm Reaming Rod with ball tip and extension, 950 mm, sterile
355.399S	Extraction Hook, sterile; for Titanium Cannulated Nails
357.42	Conical Extraction Bolt for Trochanteric Fixation Nails
394.35	Large Distractor, complete

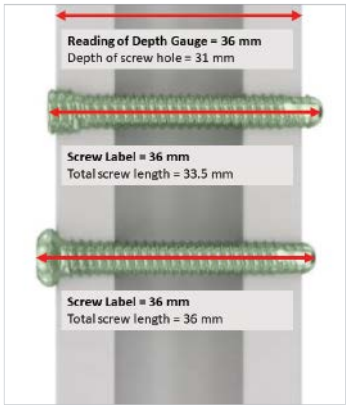
Addendum A

About Measuring Screw Length

Screw length is measured by using either of the two methods.

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

Readings do not reflect 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, considering 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 surgical technique guide.

Screw Options

TFN-ADVANCED offers two different types of retaining 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 clockwise, 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.

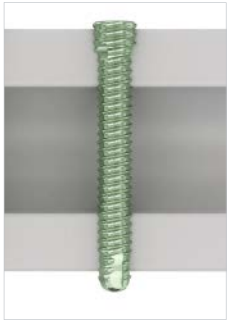
Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft with its retention pin, following the same steps as described above.

▲ Precaution:

The screw must not be fully 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 and tighten it as appropriate.

Option: Low-Profile Screw

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



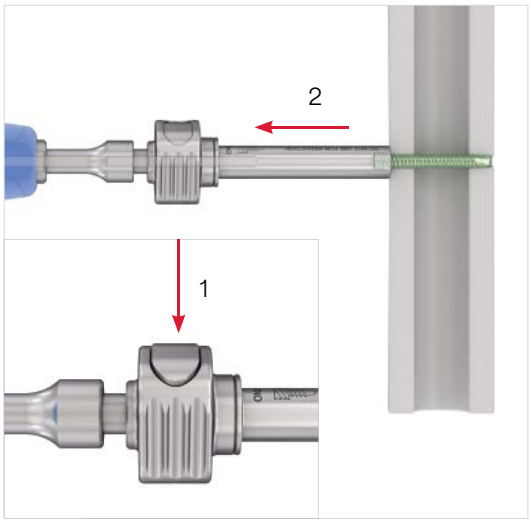
An optional sleeve is available to indicate when the screw is fully seated. Slide it over the tip of the screwdriver until it locks in place.

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

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



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 0.5mm proud of the cortex.

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 Ø 5.5 reamer (03.045.029), to make room for the screw head, and avoid excessive insertion torque.

1. Insert locking screw, Distal Locking – Short Nails (170 mm, 200 mm, and 235 mm)

Instruments

03.045.001	Screwdriver XL25*
03.045.002	Retention Pin for Screwdriver XL25

Insert the appropriate length locking screw through the protection sleeve using the screwdriver. Verify locking screw length under image intensification.

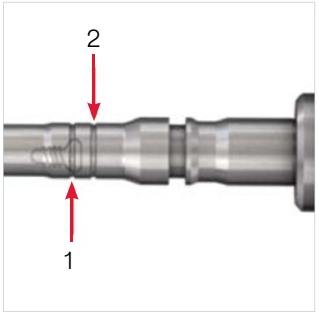
The tip of the locking screw should not project more than 4mm beyond the far cortex.

Repeat steps for the second, antegrade locking screw if desired.

Remove protection sleeves and the aiming arm.

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.



*Only for use with retaining screws.

1. Insert locking screw, Distal Locking – Long Nails

Refer to proximal locking screw guidance when inserting distal locking screw.

Instruments	
03.045.003*	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short

Insert the appropriate length locking screw using the screwdriver. Verify locking screw length under image intensification.

The tip of the locking screw should not project more than 2 mm beyond the far cortex.

*Only for use with retaining screws.

Option: Powered Screw Insertion

Instrument	
03.045.005*	Screwdriver XL25 Quick Coupling Hex 12 mm
03.045.006	Retention Pin for Screwdriver Quick Coupling, Hex 12 mm
03.140.027	Handle, large, cannulated, with Quick Coupling, Hex 12 mm
03.045.007	Screwdriver, short, XL25 Quick Coupling Hex 12 mm
03.045.008	Retention Pin for Screwdriver, short, Quick Coupling, Hex 12 mm
Alternative Instrument	
03.010.496	T-Handle Cannulated, with Quick Coupling

Alternatively, the screw can be partially inserted with a power tool, by using the screwdriver shaft (03.045.005 or 03.045.007) with its retention pin (03.045.006 or 03.045.008), following the same steps as described above.

▲ Precaution:

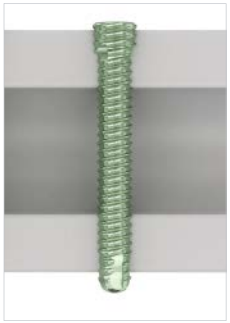
Screws must not be fully tightened with power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle (03.140.027 or 03.010.496) to bring the screw to its final position and tighten as appropriate.

*Only for use with retaining screws.

Option: Low-Profile Locking Screw

Instruments

03.045.009	Sleeve for Screwdriver
03.045.010	Sleeve for Screwdriver, short
03.045.029	Reamer, Ø 5.5 mm



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

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.

The use of a Ø 5.5 mm reamer, to make room for the screw head is recommended in hard bone.

Optional Nut and Washer Technique

■ Note:

Nut and washers are intended for use with standard Ø 5.0 mm Locking Screws only (04.045.026 through 04.045.120).

The number of nuts and washers to be used is according to surgeon preference, patient anatomy, and/or clinical condition.

Screw with Nut

Screw with Washer

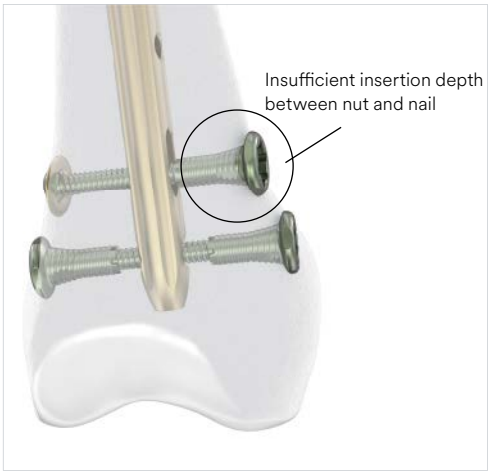
Nut with Washer

■ Note:

The nut includes a friction feature to secure nut onto the screw. The surgeon may experience tactile friction during nut insertion on the screw.

The use of nuts and/or washers may be limited in patients with a knee prosthesis, due to interference of the prosthesis, including the prosthesis box, pegs and borders.

The use of nuts may be limited by the location of the distal locking holes relative to the condyles.



■ Note:

Ensure sufficient insertion depth between nut and nail is available prior to nut insertion to avoid contact between nut and nail. If the nut contacts the nail before being fully seated, the nut may protrude off the bone.

While the actual length of the nut is 15 mm, a minimum depth gauge/drill bit measurement of 20 mm from outer cortex to nail surface is needed to ensure sufficient insertion depth for the nut.

■ Note:

If more than one screw with nut assembly is planned consider the final position of adjacent screws/nuts to avoid interference. A screw with nut in the dynamic locking position may interfere with a screw with nut in the most distal locking hole.

Two techniques are described for insertion of nuts and washers, “nut-over-screw” technique and “nut-over-drill-bit” technique.

Nut and Washer: Nut-Over-Screw Technique

1. Insert Locking Screw

Instruments	
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short
Optional Instrument	
03.045.034	Countersink, QC, 7.4mm

After drilling according to the distal locking technique, nuts and/or washers can be used with the distal, medial-lateral locking screws in the condylar region.

Countersink can be used to ease insertion of nut in patients with hard bone. Drill with countersink until the stop on the countersink contacts the cortical surface.

■ Note:

Consider anatomy and/or position the nail in the bone. A minimum distance of 20 mm measured with the drill bit/depth gauge from the surface of the bone to the outer surface of the nail is needed to ensure the nut does not contact the nail at final tightening.

Select the appropriate length screw according to the distal locking technique.

With the retention pin inserted into the screwdriver, insert the screwdriver into the screw head recess. Thread the retention pin into the screw head until secure.

■ Notes:

- **If using nut at screw head, thread nut onto screw until secure, prior to inserting screw into bone.**
- **If using washer for screw or washer for nut, position washer prior to inserting screw into bone.**
- **Prior to inserting nut into bone, forceps can be used to hold nut during screw insertion. Once screw head is seated in the nut, insertion of screw and nut assembly can continue.**
- **There are two types of washers that can be used. Select appropriate washer based on desired construct profile and nut contact area.**

Proceed with inserting screw until it is seated in the bone.

If nut is used at the screw head, the screw head should be seated flush with nut when fully inserted.

2. Insert Distal Nut and Final Tighten

Instruments

03.045.033	Driver for Nut
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short

Make an incision at the contralateral position over the tip of the screw.

Attach nut to the nut driver.

Note: If using washer for nut, position washer over nut prior to advancing the nut to bone.

Advance nut to the bone, ensuring alignment with the screw tip.

While holding the screwdriver in position, tighten nut with nut driver until seated. The nut should be fully seated to reduce soft tissue irritation.

Remove nut driver and screwdriver

Nut and Washer: Nut-Over-Drill Bit Technique

1. Insert Distal Nut

Instruments	
03.010.104	4.2 mm Three Fluted Drill Bit
03.045.033	Driver for Nut

After drilling according to the distal locking technique, nuts and/or washers can be used with the distal, medial-lateral locking screws in the condylar region.

■ Note:

Consider anatomy and/or position of the nail in the bone. A minimum distance of 20 mm measured with the drill bit/depth gauge from the surface of the bone to the outer surface of the nail is needed to ensure the nut does not contact the nail at final tightening.

Select the appropriate length screw according to the distal locking technique using the drill bit.

Keep the drill bit in position in the bone.

Make an incision at the contralateral position over the tip of the drill bit.

Attach nut to the nut driver.

■ Note:

If using washer for nut, position washer over nut prior to advancing nut to the bone.

Advance nut to the bone, ensuring alignment with the tip of the drill bit.

While holding the drill bit in position, tighten nut with nut driver until seated.

Keep nut driver engaged in nut. Remove the drill bit.

2. Insert locking screw

Instruments	
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver, short

With the retention pin inserted into the screwdriver, insert the screwdriver into the screw head recess. Thread the retention pin into the screw head until secure.

Use the screwdriver to insert the appropriate length locking screw.

■ Notes:

- **If using nut at screw head, thread nut onto screw until secure, prior to inserting screw into bone.**
- **If using washer for screw or washer for nut, position washer prior to advancing screw to the bone.**
- **Prior to inserting nut into bone, forceps can be used to hold nut during screw insertion. Once screw head is seated in the nut, insertion of screw and nut assembly can continue.**

After insertion of screw through the nail, use radiographic imaging to ensure the screw tip is aligned with the nut in the bone.

Use nut driver to provide counter-torque to nut while inserting screw through nut. Continue insertion of screw until seated.

If nut is used at screw head, the screw head should be seated flush with nut when fully inserted.

Nut should be fully seated to reduce soft tissue irritation.

Remove nut driver and screwdriver.

Insert Retaining End Cap

1. Insert end cap

Instruments	
03.045.011*	Screwdriver XL40
03.045.012	Retention Pin for Screwdriver XL40
03.043.027	T-Handle Ball Hex Screwdriver, Cannulated, Ø 8 mm

Alternative Instruments	
03.045.018†	Guide Wire Ø 3.2mm, w/drill tip, 400mm
357.399†	Guide Wire Ø 3.2 mm, length 400 mm

Endcap insertion is an optional procedure.

The grooves on the insertion handle facilitate visualization of the nail position. The first, most distal groove represents the nail end. The subsequent distances between the grooves on the insertion handle represent 5 mm and correspond to the extensions of the end caps.

End caps for femoral nails are available in extension lengths of 0 mm, 5 mm, 10 mm, and 15 mm. End caps fulfill two functions: preventing bone ingrowth into the nail and extending the nail if it is over inserted.

If desired, End Caps can be locked to the screwdriver. To do so, slide the retention pin through the back of the screwdriver until it stops. Further advance it by turning the pin clockwise, until its tip extends out through the tip of the screwdriver.

Engage the screwdriver with the recess of the recon screw and thread in the retention pin to lock the screw to the screwdriver.

*Only for use with retaining end caps.

†Available nonsterile or sterile packaged. Add “S” to product number to indicate sterile product.

Inserting the 0 mm end cap

Remove the connecting screw using the ball hexagonal screwdriver while leaving the insertion handle connected to the nail.

Insert the 0 mm end cap using the screwdriver through the insertion handle.

After the end cap is inserted, remove the insertion handle from the nail by pulling the insertion handle away from the nail.

Inserting the 5–15 mm end cap

Remove the connecting screw using the ball hexagonal screwdriver, remove the insertion handle from the nail by pulling the insertion handle away from the nail.

Engage the end cap with the screwdriver. To prevent cross-threading, align the end cap with the nail axis and turn the end cap counterclockwise, until the thread of the end cap aligns with that of the nail. Turn the end cap clockwise to thread the end cap into the nail until it is fully inserted.

Remove screwdriver.

■ Notes:

- In case of difficulties removing the connecting screw or insertion handle, push the insertion handle towards the medial or lateral side to neutralize soft tissue pressure.
- The end cap protects the nail connection threads from bone ingrowth to facilitate removal and extends the height of the nail if over-inserted.

Implant Removal

Implant removal is an optional procedure.

1. Remove end cap and locking screws

Removal of End Caps	
03.045.011	Screwdriver XL40
03.045.012	Retention Pin for Screwdriver XL40
Alternative Instruments	
03.045.013	Screwdriver XL40, extra long
03.045.014	Retention Pin for Screwdriver XL40, extra long
Removal of Locking Screws	
03.045.001	Screwdriver XL25
03.045.002	Retention Pin for Screwdriver XL25
Alternative Instruments	
03.045.003	Screwdriver, short, XL25
03.045.004	Retention Pin for Screwdriver XL25, short

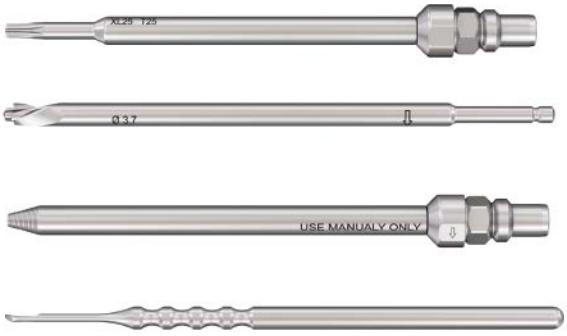
Clear the recess of the end cap and the locking implants of any ingrown tissue. Remove the end cap using the screwdriver.

Remove all locking screws except one proximal locking screw using the screwdriver. Refer to retaining screw guidance above, to lock screws to suitable screwdrivers.

■ Note:

Retaining end caps are compatible with existing T40 screwdrivers, and retaining screws are compatible with existing T25 screwdrivers.

Screw Removal Tools	
03.045.030	Extractor Shaft for XL25
03.045.031	Curette for XL25
03.045.032	Extraction Screw, conical
03.900.001	Straight Sharp Hook



2. Remove final locking screw

Instruments	
03.010.000	Extraction Screw for Tibial and Femoral Nails
03.010.170	Hammer Guide
321.160	Combination Wrench Ø 11.0 mm
Removal of Locking Screws	
03.045.001	Screwdriver XL25
03.045.002	Retention Pin for Screwdriver XL25

Before removing the final locking screw, screw the extraction screw into the nail and tighten it using the ratchet wrench. The locking screw will prevent nail rotation as the extraction screw is tightened.

Attach the hammer guide to the extraction screw. Remove the remaining screw using an XL25 screwdriver.

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- Reduced Procedural Complexity
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